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Protection of traditional knowledge: Deliberations from a transnational stakeholder dialogue between pharmaceutical companies and civil society organizations

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DISCUSSION PAPER



SP IV 03-102

Protection of Traditional Knowledge — Deliberations from a Transnational Stakeholder Dialogue Between Pharmaceutical Companies and Civil Society Organizations

Achim Seiler, Wolfgang van den Daele, Rainer Döbert

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Protection of Traditional Knowledge—Deliberations from a Transnational Stakeholder Dialogue Between Pharmaceutical Companies and Civil Society Organizations

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SUMMARY STATEMENT

This report summarizes deliberations over the *Protection of Traditional Knowledge* 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 nongovernmental organizations as well as renowned experts in the field of intellectual property rights.

This paper briefly sketches the project and the process of the Dialogue. The products of the process are the opinions, both concurring and dissenting, that the participants reached on the Protection of Traditional Knowledge, subsumed in the final report to the WBCSD that emerged from the project. This paper also reviews documents (Circulars) from the proceedings, which further illustrate the dynamics of the deliberations, and the range and direction of arguments exchanged by the participants.

ZUSAMMENFASSUNG

Das Diskussionspapier stellt die Ergebnisse dar, die im Rahmen eines vom World Business Council on Sustainable Development (WBCSD) initiierten Stakeholder Dialogs zum Thema Schutz des traditionellen Wissens erreicht worden sind. Ziel des Dialogs war es zu untersuchen, welche Optionen Unternehmen haben, öffentlichen Kritiken am geltenden Regime des geistigen Eigentums durch Anpassung ihrer Strategien Rechnung zu tragen. Beteiligt waren an dem Dialog Vertreter von großen pharmazeutischen Firmen und von transnational operierenden Nichtregierungsorganisationen, sowie Experten des Rechts des geistigen Eigentums.

Das Diskussionspapier skizziert Charakter und Verlauf des Dialogverfahrens. Im Zentrum stehen die Ergebnisse zum Thema Schutz des traditionellen Wissens, wie sie in den vom World Business Council herausgegebenen Endberichts des Stakeholder Dialogs eingegangen sind – mit der Kennzeichnung der jeweils übereinstimmenden oder abweichenden Positionen der Teilnehmer. Es folgt eine kurze Diskussion dieser Ergebnisse. Im Anhang werden zentrale Dokumente des Verfahrens (Circulars) abgedruckt, die Einblick geben in die Dynamik der Verhandlungen und die Reichweite und Richtung der von den Teilnehmern ausgetauschten Argumente.

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1. The Project: In Search of New IPR Policy Options for Pharmaceutical Companies

In 2001 the World Business Council for Sustainable Development (WBCSD) launched a project to engage transnational pharmaceutical companies and non-governmental organizations in a dialogue over the proper role and limits of intellectual property rights (IPRs) in the development of medical biotechnology. Project Working Groups dealt with three issues areas that raise broad public concerns and confront companies with the need to reconsider their IPR policies: Access to Human Genetic Resources, Protection of Traditional Knowledge, and Access to Essential Medicines.

The WBCSD is a coalition of 130 international companies sharing a commitment to sustainable development. Council members considered 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 on what the companies themselves might contribute in order to resolve contested IPR issues, given the economic criteria under which they operate. Participants, of course, had to be aware of existing legal regimes of IPR (in particular, the Agreement on Trade-Related Aspects of Intellectual Property Rights, "TRIPS"), but they were expected to explore options for societal self-regulation within and beyond those regimes.

Some of the rationales and premises underlying the project are described in the following excerpts from the document that outlined the project and called for the participation of the stakeholders¹:

Conflicts over IPRs

Existing regimes of IPRs are contested. Companies would defend them as a suitable and, in fact, necessary strategy to secure a return on the investments necessary to produce useful knowledge. ... Companies hold that these regimes serve a social and not merely a private function: By providing incentives for innovation and mobilizing resources for research IPRs will accelerate and multiply technological development that benefits the whole society. In contrast, critics argue that IPRs, particularly patent protection, in fact create unfair monopolistic advantage and concentrated market control; they defend excessive prices and profits, and deprive societies of the benefits of rapid dissemination and use of new knowledge. ... Strong IPRs are suspected of concentrating strategic knowledge in the hands of some exclusive global business players, making it even more difficult for developing countries to gain access to and derive benefits from new technologies. This further exacerbates already existing imbalances in the world economy.

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¹ Framework for a Stakeholder Dialogue Proposed by the World Business Council for Sustainable Development (WBCSD), downloadable from the internet at: http://www.wz-berlin.de/ipr-dialogue>.

Emerging Patterns of Global Governance

While the contested issues may ultimately require national or international regulation, regulatory policies may be slow. ... Strategies that involve non-state actors (including the business sector) in processes of negotiated policy making and private-public partnerships are likely to coexist with legal international regimes in the emerging processes of global governance. Such strategies give political mandate (and corresponding duties) to global players from the private sector of business and from the civil society sector of non-governmental organizations. This implies that business enterprises are able and willing to address criteria beyond short-term profit making and shareholder value in their corporate policies, and 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.

The Notion of "Embedded" Economy

The WBCSD project assumes as given the premise that companies operate on markets that are ... to a certain extent at least, also communities where people act as citizens and as stakeholders pursuing social, political, or cultural concerns beyond purely economic interests. ... The WBCSD is aware of the social and political embeddedness of the market economy. In fact, such awareness was the very reason for establishing the Council in the first place. The question is, of course, how such awareness can be translated into operational rules for corporate management in a competitive, transnational environment. To expose companies as visibly as possible to the concerns of stakeholders will be a necessary condition. In the IPR case, the challenge is 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.

2. The Process: Deliberations with Stakeholders

IPR issues are discussed in numerous formal and informal arenas. The WBCSD project was specific, in that it convened conflicting parties in a sustained effort to sort out views, positions, and options through dialogue. While "dialogue" is the accepted norm in dealing with embattled political questions, it is seldom the social reality. In most settings the parties lack the time or capacity, or mandate to engage in extended deliberations over the arguments put forward. The WCBSD project intended to break that pattern, in keeping with models provided by previous projects such as the Keystone Dialogue or the Crucible Group.²

The IPR Dialogue Process involved some 50 participants: representatives from companies and civil society organizations, experts on IPR, and a number of

² See, for example, The Crucible Group: People, Plants, and Patents—The Impact of Intellectual Property on Trade, Plant Biodiversity, and Rural Society, IDRC, Ottawa 1994; or, The Crucible II Group: Seeding Solutions, Vol. 1: Policy Options for Genetic Resources, IDRC, Ottawa 2000, and Vol. 2: Options for National Laws Governing Control Over Genetic Resources and Biological Innovations, IDRC, Ottawa, 2001.

observers from international organizations or governmental bodies. It included two face-to-face meetings, one conference in the beginning to decide the agenda and the rules of the Dialogue (Montreux, May 2001), and one conference towards the end (London, February 2002) to discuss the contents and procedure for drafting the final report of the project. Communication before, during, and after the conferences proceeded via internet exchange.

Communication through the internet was vital for the project. Without it, efficient cooperation of participants from 15 countries around the world would not have been possible. The Montreux conference gave the mandate to organize and moderate the internet exchanges and conferences to a team of scientists from the Social Science Research Center Berlin (Wissenschaftszentrum Berlin fuer Sozialforschung) (WZB).³ The WZB team was expected to provide surveys of arguments on the topics that the participants put on the project agenda. Moreover, the members of the team screened the transactions of the Working Groups that dealt with these topics at the first conference, and analyzed related documents and literature proposed by the participants. The surveys of arguments were circulated back to the participants for response, further questions, and criticism. The responses, in turn, were synthesized and presented to the participants to be discussed at the London conference.

This procedure gave the WZB team a major role in preparing and supporting the deliberations throughout the project. Such a role was indispensable in view of the complex issues and interactions that had to be managed within the time scheduled for the Dialogue. It was understood that the WZB team would guarantee transparency of all transactions, and act according to the rule that full control over the Dialogue process rest with the participants. This rule implied, in particular, that the participants decide what to include in a report from the project, or what to add to such a report as commentary or dissenting opinion.

Formal supervision of the Dialogue process was exercised by a Steering Committee established by the participants at the first project conference in Montreux. The Steering Committee was in charge of organizing, compiling, and editing the final project report.⁴

³ The WZB team included: Wolfgang van den Daele, Rainer Döbert, Achim Seiler and Jost Wagner. At the London conference Michael Lesnick and Heather Lair (Meridian Institute, Washington) acted as a facilitators.

⁴ Project Steering Committee: 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.

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 Dialog Process to the WBCSD	

^{*}Documents indicated in bold are included in this report insofar as they relate to PTK.

3. The Product: Conclusions on the Protection of Traditional Knowledge from the Final Report to the WBCSD⁵

The following pages contain an excerpt from the Final Report of the IPR Stakeholder Dialogue (part 2, "Protection of Traditional Knowledge", pages 20 to 29). The footnote numbers in this excerpt correspond to the numbers in the original text.

5 World Business Council for Sustainable Development (ed.), Intellectual Property Rights in Biotechnology and Health Care—Results of a Stakeholder Dialogue, July 2002. This document can be downloaded from the WZB and WBCSD websites, respectively: see http://www.wz-berlin.de/ipr-dialogue/ or http://www.wbcsd.org/

Protection of Traditional Knowledge (TK)

Concerns and Perspectives

Borrowing from Art. 8 (j) of the Convention on Biological Diversity, "traditional knowledge" is usually described as "knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles". The protection of TK was included as a topic in the Dialogue Process on intellectual property rights because the participants shared the underlying assumption that such knowledge constitutes a potentially valuable resource for medical research and the development of new medicines, and that, therefore, conditions and rules need to be defined for how companies can obtain access to and use TK.

Beyond this basic assumption, however, participants differd profoundly in the concerns and perspectives they associate with the protection of TK. Companies tended to take a narrow perspective and focus on questions of how TK can be used legitimately for R & D in a business framework. Companies acknowledged that they must respect the rights of the holders of TK and negotiate equitable sharing of benefits with them. What companies want are reliable and accepted rules that provide clear guidance for how they should proceed in complying with these obligations, which protect them from criticism if they act accordingly. Companies feel that they need criteria to evaluate whether an envisaged R & D activity is going to infringe upon protected TK, and they need to identify the holders with whom they can negotiate consent and benefit sharing for the use of such knowledge. Companies were concerned that, because of the lack of consensus over the rules and the high transaction costs involved in negotiating access to TK, the use of such knowledge may not become a realistic option for commercial R & D. They were also concerned with what they see as an unwarranted tendency among parts of the public to launch moral campaigns ("biopiracy") against companies that use TK in R & D, regardless of whether or not legal rules and contractual obligations have been complied with.

Indigenous peoples (and NGOs and experts speaking on their behalf) took a much broader perspective. For them protection of TK cannot be reduced to questions of access to knowledge and of intellectual property. They consider it instead as integrated with their ongoing struggles to defend the integrity of their cultures and regain the autonomy of their communities. Protection of TK is linked with issues of political self-determination, land rights, the tensions between indigenous and national communities, and issues of (in)justice in the North-South relationship. These broader concerns have profound implications for how the more specific questions of access to and use of TK are addressed by indigenous peoples. Their foremost interest is to have their own rules and values, as embodied in their customary laws, acknowledged and applied in dealing with these questions. The customary law also provides rules for ownership of knowledge (intellectual property) that respect the integrity of the culture and take the nature of invention in the realm of TK and the needs of indigenous

²⁰ The respective passage on protection of traditional knowledge in Art. 8 (j) of the CBD reads in full:
"... to respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices."

communities into account. Modern regimes of IPRs that apply criteria of novelty, industrial applicability, and non-obviousness to demarcate protected knowledge, are considered as inherently biased and unfair. A point of contention in this respect was the modern rule that knowledge available in the public domain can be used without consent or benefit sharing: "People have to recognize that knowledge has its owner and that those owners should be recognized and compensated in some way, regardless [of whether] that knowledge is in the so-called public domain, which is in itself a pure western concept. Bio-cultural space should be the basis of the protection of traditional knowledge (land rights, cultural rights, self-determination), otherwise the richness and maintenance of that knowledge will get physically lost" (participant, representing an indigenous peoples' organization).

The deliberations in the *Dialogue Process* could not discuss the broader contexts of the protection of TK at great length; but, in principle, the companies acknowledged the concerns raised by the indigenous peoples. The companies only pointed out that they cannot become involved in political disputes between the indigenous communities and their nation states and that negotiations over access to TK seem to leave little space to address these broader issues in a meaningful way. On the other hand it was accepted that negotiations over access and benefit sharing could consider contributions that the indigenous peoples recognize as supportive of their broader concerns.

Companies declared their commitment to honor the customary law and accept it as the binding framework whenever they approach an indigenous community for access to TK. A more difficult question was what rules should apply if the TK has been dispersed to the public domain and is, technically, accessible without disclosure. In such a case, a collision may exist between the customary law of the community that was the original holder of that knowledge and the rules of modern IPR regimes under which companies operate outside negotiations with indigenous communities. The participants did not resolve this issue. They discussed, however, some proposals, also accepted by industry, to modify the public domain rule. Some modification is also suggested by the guidelines issued by the European Chemical Industry Council (CEFIC),²¹ which may be appropriate to accommodate conflicting interests better.

The participants did not try to demarcate which TK should be protected as intellectual property and which not. It was understood that the customary law would have to provide the respective guidance in the case that a company seeks access to TK through disclosure by the indigenous community. 22

The following statements summarize the findings of the *Dialogue Process*. They indicate both convergence and divergence of opinion. They should be read in context and with a view to the points raised in this introduction. Proposals for alternative wording and dissenting views are registered in footnotes. The statements focus on what companies can do to gain legitimate access to, and use of, TK. The participants of the Working Group agreed that the broader issues associated with the protection of TK should be acknowledged explicitly in a final section of the paper.

²¹ CEFIC Position Paper: "The Chemical Industry Comments on the Legal Protection of Traditional Knowledge & Access to Genetic Resources Patenting", November 2000 (recently updated), downloadable under http://www.cefic.be

²² The WIPO also relegates the definition of what constitutes TK and how that knowledge should be protected to the indigenous and local groups themselves. See: "Draft Report on Fact-Finding Missions on Intellectual Property and Traditional Knowledge, Summary, Reflections and Conclusions", July 3, 2000, p. 4, downloadable under http://www.wipo.int/globalissues/index-en.html

A. Preamble

- 62. The group urges the acknowledgement of the cultural, spiritual, and economic value of traditional knowledge (TK), innovations and practices, especially to the communities themselves.
- 63. The group also agrees that protecting and maintaining TK is an urgent priority and that all stakeholders must respect the cultural integrity of the holders of TK and the laws on which their communities are based, 23 in keeping with established international human rights standards. 24
- 64. In accordance with a recent statement by the International Chamber of Commerce, ²⁵ the group also understands that the IPR system reflects a western conception of innovation and as currently implemented world wide respects above all the economic interests of current users/industrialized countries, and also that the formal IPR system inadequately accommodates traditional customs, norms and values and systems of governance relating to knowledge.
- 65. This imbalance is inherently unfair and needs to be addressed.²⁶ In this respect, the group acknowledges work undertaken by WIPO to better protect

²³ One participant (NGO) insisted that the expression "and autonomy" be inserted (again) and replace the phrase "and the laws on which their communities are based". Since the group could not agree in London on the words "and autonomy", and one participant from industry explicitly emphasized that he would not be able to sign any document which obliges his company to possibly interfere with national legislation, compromise wording was formulated and inserted by the WZB Team. Since a few other participants indicated that they did not have any problems with this version of the preamble at all, and since the WZB Team had not received any objections from the side of the indigenous participant, the Steering Committee proposed to leave the phrase as it is.

²⁴ One participant (non-industry expert) requested that reference be made to international human rights standards by which traditional communities must also abide. The Steering Committee proposed to take this recommendation into account.

²⁵ ICC: "A particular grievance is an imbalance of rights. The new products and technologies developed by multinational companies can be protected by patents and other intellectual property rights, while valuable 'traditional knowledge', accumulated in indigenous communities over generations, is generally unprotected by modern legal systems, and may be exploited freely by all. This perceived inequity has led to vociferous calls for the protection of 'traditional knowledge', to provide a counterbalance to the rights of companies in new technology. Increasingly, such calls are given credence and have built up political momentum, to the point at which governments may find it necessary to act." Again, one participant (NGO) asked for removal of the wording: "In accordance with a statement by the International Chamber of Commerce" stressing that the International Chamber of Commerce was neither the first nor the only institution to take notice of the unilateralism in the Western IPR system. Since this formulation emphasizes the fact that the group, as a whole, drew the conclusion that the IPR system, as it is, reflects predominantly Western values; and since the reference to this statement by the International Chamber of Commerce (a) was necessary to get the consent by another participant (industry) and (b) does not appear to be wrongly situated, given that the project was initiated by the industry; the Steering Committee proposed to leave the preamble as it is.

²⁶ New and extended formulation proposed by participant (NGO): "This imbalance is inherently unfair and needs to be changed. To achieve a balance, the Western granting practice should diminish the rights of IPR holders, with the objective to not restrict access to knowledge, especially when basic human rights such as the right to food, health, or education are concerned. Thinking about the protection of TK, we should bear in mind that it is not the traditional knowledge management system that has sparked problems in the Western IPR system, but rather the Western IPR system that leads toward privatization, monopolization and misappropriation of traditional knowledge. Accordingly, corrections and adjustments have to start with the Western IPR system."

- traditional knowledge and the interests of its holders and to explore TK holders' own informal IPR-like regimes based on customary law.²⁷
- 66. There have been many recent cases of commercial use of biodiversity involving traditional knowledge that need to be studied for useful lessons.
- 67. Traditional communities and individual experts among them who generate, reproduce, sustain, and refine traditional knowledge²⁸ have a right to a fair and equitable share of benefits arising from the commercial use of their knowledge.
- 68. Traditional communities and TK holders have the right to say "no" to commercial use of their knowledge.
- 69. Companies must acquire the prior informed consent (PIC) of TK holders before they seek IPR protection of innovations arising from their research.

B. Objectives and Common Ground

(1) Basic Objectives of Indigenous Communities²⁹

- 70. Indigenous peoples consider the protection of TK as an element of their broader struggle for self-determination, land rights and political autonomy.
- 71. Indigenous peoples see an urgent need to protect, promote and conserve TK, because TK is a binding and preserving factor for indigenous communities. However, because of lack of recognition and compensation, TK is losing significance for the communities and is disappearing at an accelerating rate.
- 72. Indigenous peoples are concerned that the value generated through TK is not adequately recognized and compensated. It should be acknowledged that the protection, promotion and conservation of TK are important for global environmental security and food supply.
- 73. Indigenous peoples seek protection to prevent unauthorized appropriation of TK and to ensure a fair and equitable sharing of benefits arising from the use of the knowledge. It must be prevented that TK is appropriated, adapted, and patented with no compensation for the custodians of the knowledge and without their prior informed consent.

²⁷ One participant (non-industry expert) requested that the existence of traditional IPR protection mechanisms be emphasized in the preamble. The Steering Committee decided to take this recommendation into account.

²⁸ One participant (non-industry expert) insisted that the achievements of individuals be mentioned separately, in accordance with analogous comments made by several other participants in the course of the dialogue. The Steering Committee proposed to take this recommendation into account.

²⁹ One participant (NGO) questioned in principle the legitimacy of the statements in this paragraph, since none of them had been put forward or explicitly consented to by a representative of an indigenous group. However, the text was communicated to the representatives of the indigenous peoples and did not meet with any objections. The Steering Committee considers the statements made in this paragraph to be a fair representation of main objectives.

- 74. Indigenous peoples affirm that their customary laws should be applicable in regulating the use and dissemination of their own knowledge, and that these laws should be enforceable.
- 75. For indigenous people, protection of TK and changes in the IPR system are necessary to bring equity to the essentially unjust and unequal relations between the traditional and the modern parts of the world.

(2) Basic Objectives of Companies

- 76. Companies want access to TK that could be useful for commercial research and product development. To this end, they need to know what the social actors and communities involved consider as lawful and rightful behavior.
- 77. Companies therefore strongly advocate that rules be set up that are generally accepted and clearly tell when and how TK can be used legitimately by private companies. Most important in this respect are rules to demarcate the protected TK and identify its legitimate holders. Companies must be able to evaluate whether envisaged activities are likely to infringe upon protected TK. And they must be able to know whom they should address to negotiate consent and benefit sharing.
- 78. Such rules should be voluntary to allow flexibility and learning. If the rules bring about successful cooperation in the use of TK, they will become paradigmatic and, as a matter of fact, binding.

(3) Common Ground: Routes to Be Taken

- 79. Accepted rules/regulations that resolve the issues of legitimate access to TK at the international level are still under development. Existing rules/regulations are limited to national territories.³⁰
- 80. Participants share the understanding that all those involved in access to TK necessarily operate under conditions of normative or moral uncertainty. General legal frameworks that may apply (such as the ABS Guidelines of the CBD) do not provide specific guidance.
- 81. Companies acknowledge that traditional (indigenous) knowledge is a potentially valuable source of creativity and invention outside the communities from which the knowledge originates. Despite the uncertainty regarding the rules for access, the companies are interested that such knowledge is made available for commercial use. Private interests might to a certain extent resonate with intentions of the holders of TK to make some of their traditional practices and achievements accessible for commercial, profit-making purposes.
- 82. When seeking access to traditional knowledge, companies commit themselves to acknowledging the customary laws according to which the societies of the holders of such knowledge are organized, and to basing their

³⁰ In this respect, one participant recommended that results be taken into account, which were attained elsewhere. See, for instance, the "Pew Ethical Guidelines" in Eubios Journal of Asian and International Bioethics 5 (1995), pp. 38-40 http://www.biol.tsukuba.ac.jp/~macer/EJ52I.html.

- approaches on those established customs when negotiating consent and benefit sharing.
- 83. Companies and holders of TK agree that, in order to cooperate under conditions of normative uncertainty, and in the absence of established models of best practice, some procedural virtues must be applied: flexibility, patience, and allowance for trial-and-error in good faith. The cooperation should be based on mutual respect.
- 84. Companies acknowledge that trust building is essential in dealing with traditional (indigenous) communities.
- 85. Companies accept that they cannot disseminate, use, or sell the knowledge disclosed to them under an agreement, without the free and informed consent of the holders of TK. The same applies to third parties (universities, brokering companies or follow-up developers whom the companies involve. The holders of traditional knowledge should have the right to refuse this permission
- 86. Companies/third parties cannot obtain patents, copyrights, or other legal IPR protection for the traditional knowledge of indigenous peoples disclosed to them, as well as for any creation/invention based/developed on this traditional knowledge, without adequate documentation of the free and prior informed consent of the holders of the traditional knowledge. Companies/third parties ensure the labeling and correct attribution of traditional knowledge of indigenous peoples whenever they offer for public display or sale products based on traditional knowledge.
- 87. In the current situation, where the standards for the protection of TK are not clearly spelled out, examples of best practices can provide a useful foothold for the creation of new rules. Such examples can also give indigenous communities a common starting point for negotiations. Examples of best practice could eventually be used as the basis for national and international legislation.

(4) Common Ground: Mistakes to Be Avoided

- 88. Companies should refrain from any attempt to get access to TK by acts that imply breach of confidentiality, espionage, or other invasions of the privacy of indigenous communities.
- 89. Companies should not file patents or apply any other instrument to claim rights over TK without the consent of the holders. Such claims would violate the respect and acknowledgement owed to the holders of TK. In most countries such patents should not be granted anyway because existing TK constitutes prior art. In the legislation of many countries the right to obtain a patent or other legal protection of an invention based on traditional knowledge or derived therefrom is also denied if the free and informed consent of the holders of traditional knowledge is not adequately documented. The participants acknowledge that the latter should be extended to all countries and observed by applicants.

- 90. Holders of TK and stakeholders speaking on their behalf should refrain from denouncing access and benefit sharing agreements in public as being immoral³¹ as long as such a reproach cannot be sufficiently substantiated.
- 91. Companies should avoid instrumentalizing apparent inequalities in bargaining power to their own advantage. They should contribute to capacity building on the part of the indigenous partners and provide specific guarantees to indigenous communities to strengthen the communities' bargaining position. Such measures are an important element of trust building.

C Exploring the Options and Obligations for Companies

(1) What Companies Should Do Within Contractual Relationships with Holders of TK?

- 92. Companies should declare that they acknowledge the local rules indigenous communities have with respect to the use of TK. They should commit themselves to abide by those rules and to follow the underlying principles, also in the run-up to any such negotiations.
- 93. Companies should accept the definition of indigenous communities as to who the rightful holders of TK are. Customary law may rule that the community (and not the individual) is the holder. Such law can be respected by involving the community in any negotiation at least having it authorize the contract. Companies should be prepared to accept that such a procedure might be a time-consuming and iterative process.
- 94. There is always a possibility that third parties (individuals or communities) claim that the contracting party is in fact not a rightful holder of the negotiated TK. If partners fail to establish their right to the traditional knowledge, companies can retreat from the contract and, instead, enter into negotiations with the legitimate holder of that knowledge.
- 95. Disputes over what constitutes TK may be endless and divisive. Companies should accept as TK what their partners disclose as TK. They can decide not to close a deal if they think the claims of their indigenous partners are too broad or otherwise unwarranted.
- 96. Companies should be flexible with respect to the public domain question. Whether the TK that the indigenous partner holds and offers to disclose could also be retrieved from what, in modern terms, is called the public domain, may not make much difference. The indigenous partner delivers an intangible good that the company may not have. This should be recognized and compensated, regardless of whether or not rules exist that make such an approach binding. Companies can negotiate the price for the information. They will certainly value the disclosure of TK that is secret or not widely

³¹ One participant asked to replace the whole paragraph with the following formulation: "Holders of traditional knowledge and civil society organizations should denounce ABS agreements in public, [if] they are immoral and/or illegal. They should not do so, [if] the agreements are obviously correct."

- known more than TK that can (with some effort) also be retrieved from generally accessible sources.³²
- 97. Companies agree, in any case, to reward and to compensate the use of TK disclosed to them. Companies can consider any type of BS the indigenous partners wish. BS may also include non-monetary measures not directly related to the use and commercial exploitation of the TK, which strengthen the autonomy and development of indigenous communities.
- 98. In a business framework, companies must measure the accumulated amount of all benefits to be paid against the economic value they assign to the TK. They can (and probably should), however, also explore options to transcend the narrow business frame, and consider wider symbolic and political values to be derived from successful negotiations with indigenous communities. If easing the troubled North-South relationships or enhancing the societal acceptance of the companies are taken into account as objectives, additional BS agreements may become viable.
- 99. Companies take the broader social and political concerns of indigenous partners into account wherever this is compatible with the negotiated subject matter.

(2) What Companies Should Do Outside Contractual Relationships

- 100. Companies must comply with existing regulations (international and national) for access to TK. If such knowledge is connected with genetic resources, the requirements foreseen under national or international law for obtaining access to those resources must be fulfilled.
- 101. Companies should not seek access to, or use, TK that is clearly identifiable as the knowledge of an existing indigenous community (or individuals from such a community), without PIC.
- 102. TK may have been created or possessed simultaneously in various indigenous communities, or proliferated through diffusion and learning to other communities. In those cases, each community which practices (and can disclose) the TK should be considered as rightful holder who can legitimately authorize the use of that knowledge. It should be sufficient to enter into access and benefit sharing negotiations with only one of those communities.³³

³² One participant (NGO) wanted to add the following statement: "Companies might commit themselves [to not] seek access to TK-related biological resources from ex-situ collections such as botanical gardens, zoos, or gene banks anywhere else in the world, once they have been informed about the connectedness of those resources to specific traditional practices of indigenous communities and the value of their use". This statement does not reflect a consensus among participants. Representatives from industry acknowledge that this issue needs to be regulated. They feel however that this issue was not dealt with sufficiently in the Dialogue Process. The Steering Committee proposed to shift this statement to the footnotes for further consideration.

³³ The question of the relationship between various communities who hold (and can disclose) the same piece of TK has triggered some discussion. One participant (non-industry expert) proposed that the following statement be included: "Companies should also consider voluntary contributions to the further maintenance of the traditional lifestyles of other communities practicing this specific type of traditional knowledge, if [those communities'] lifestyles comply with the CBD stipulations in Art. 8 (j), i.e., [that] the traditional knowledge is actively practiced. Contributions to a specially

- 103. Companies should not be obliged to seek PIC for the use of knowledge that has once been generated by an indigenous community but is now generally known. Even if it is still possible to identify the original holders, one has to accept that knowledge from one culture can become incorporated into the knowledge system and the social practices (craftsmanship, industry or scientific disciplines) of another culture.
- 104. Companies should accept that TK is considered novel and not in the public domain, if it has not been publicly disclosed by anyone outside the indigenous communities by means of television, radio, magazine, articles or academic publications.
- 105. In addition, companies should accept that publication in a highly specialized journal may not constitute evidence that a piece of traditional knowledge has become public domain in a patent law sense, as long as such knowledge has not been incorporated into the knowledge system outside the traditional community. For example, disclosure of traditional practices in an ethnographic journal could be considered as a form of publicly accessible registration of TK for (and on behalf of) the original holders, and hence not diminish, but enhance their rights. Companies should acknowledge that they need to negotiate for consent and benefit sharing with the holders (provided these can still be identified), if they (companies) want to use TK that has only been disclosed in ethnographic (ethno-botanical, etc.) descriptions.
- 106. Companies acknowledge the proposition of the European Chemical Industry Council (CEFIC) that special (sui generis) legal systems might be devised that make TK even when it has already been widely published or known outside the communities protectable subject matter again, under certain circumstances in favor of the holders of such knowledge.
- 107. Rules of respect for the integrity of cultures require that indigenous communities have a right to object to uses of their knowledge that are deeply offensive to their culture, e.g., the commercial uses of "sacred" TK. Accordingly, companies should abstain from any such uses. On the other hand, ³⁴ concepts of sacredness are culture-bound. TK may belong to more than one community and may be held sacred in one, but non-sacred in the other. In this case rules of respect for cultural diversity require that each community can live up to its own traditions and no one claims censorship over the other.

devised fund could be an appropriate mechanism to deliver a company's support to those communities." Another participant (NGO) suggested recommending that the principles agreed upon in the International Seed Treaty of the FAO should be applied, according to which a multilateral system for access and a fund for compensation is envisaged. Reference to the FAO-Treaty will be made in the section entitled "Protection of Traditional Knowledge and the Legitimate Interests of Its Holders in the Broader Context".

³⁴ One participant (NGO) asked that these last two sentences be deleted — beginning, "On the other hand concepts of sacredness ...", and ending with, "... and no one claims censorship over the other" — since the aspect dealt with here would deserve more in-depth discussions.

D. Protection of Traditional Knowledge and the Legitimate Interests of Its Holders in the Broader Context

- 108. Companies acknowledge that the fair and equitable use of TK is embedded in a larger context constituted by the indigenous peoples' quest for self-determination, land rights, and political autonomy, as the basis for the maintenance of their traditional lifestyles. Companies should take these broader social and political concerns of their indigenous partners into account wherever this is compatible with the negotiated subject matter.
- 109. Indigenous communities should acknowledge that negotiations with business companies over access to TK might not be an arena in which the broad political issues they also have on their agenda such as self-determination and compensation for historic injustices can effectively be dealt with.
- 110. Companies commit themselves to acknowledge the customary rules indigenous communities have, both in the context of a specific contractual relationship as well as in the run-up to any negotiation undertaken to reach an agreement on access and the utilization of indigenous knowledge.
- 111. Companies fully support the principles underlying the Convention on Biological Diversity and abide by its stipulations, especially when it comes to negotiations with the holders of traditional knowledge about access and benefit sharing. They also emphasize the importance of the multilateral system for facilitated access as envisaged by the FAO International Treaty on Plant Genetic Resources for Food and Agriculture, and the stipulations contained therein with regard to the protection of TK.
- 112. Companies should ensure that their intellectual property rights do not run counter to the objectives of the Convention on Biological Diversity, but are supportive of those objectives as well as the underlying principles (e.g., indication of PIC, declaration of origin, and ABS agreements when it comes to the granting of patents). Equally, they ensure that their IPRs are in line with the requirements of the FAO International Treaty on Plant Genetic Resources. Companies should be open to consider whether the system of facilitated access as agreed upon in the FAO-Treaty could be adapted to other subsets of biological diversity.
- 113. Indigenous peoples' rights of control over their knowledge should last as long as the community use of that knowledge is active and efforts are made to keep it confidential within the concerned group of holders of traditional knowledge.
- 114. Companies should commit themselves to support all initiatives for the protection of traditional knowledge whether inside or outside the established IPR-system. This comprises the acknowledgement of work undertaken by WIPO and elsewhere to strengthen the position of TK holders and to prevent the misappropriation of their achievements. Industry should support necessary changes in the established IPR system as well as current granting practices. Companies acknowledge that these modifications should be reflected by International IPR requirements such as TRIPS or potential follow-up agreements.

4. Discussion: Steps towards Accommodating Diverging Communities and Cultures

This section gives a brief analytical review of the results of the stakeholder deliberations by the WZB team. It discusses some of the achievements from, and limitations of, the cooperation during the Dialogue procedure, and relates the results of the Dialogue to various contentious issues in ongoing debates over the protection of TK. The participants will, of course, have to give their own assessments of what they achieved or did not achieve. Additional insight into how the deliberations proceeded can be gathered from the "Circular" to the participants of working group II and "Argumentation" on traditional knowledge (see appendices I and II, respectively). It must be noted, however, that the Final Report presented by the Steering Committee is the only officially authorized text on the results of the Dialogue procedure.

4.1. Acknowledging the Issues Behind the Protection of TK

Representatives of indigenous communities made it clear that they would not enter a dialogue on the protection of TK without the acknowledgement of their deeper underlying concerns for the integrity of their cultures, land rights, political self-determination, and compensation for historical oppression and exploitation. Otherwise they felt that they could be seen as just promoting the case for companies who want rules determining how they (companies) can use and obtain IPRs on TK. The participants included such acknowledgement repeatedly in the Final Report (e.g., nos. 62, 70, 108),6 and accepted this recognition of their concerns as a starting point for the working group on PTK (see "Circular", appendix I, and "Argumentation", appendix II).

Some companies, on the other hand, insisted that they could not become allies of the indigenous communities in their political battles with national governments. This was cautiously conceded (no. 109).

4.2. Addressing Injustice in the IPR System

In the section pertaining to traditional knowledge, the Final Report states that existing IPR regimes are inherently unfair because they grant exclusive rights over knowledge generated in modern systems of innovation, but that they do not do so for TK accumulated in indigenous communities (no. 65). For indigenous representatives and NGOs as well as experts associated with them, this statement was a baseline for the discussion in the Dialogue. The companies let this statement pass, but some of them attached great importance to adding explicitly that it reflects an

⁶ These numbers refer to the TK-related conclusions of the Final Report; see section 3, excerpt, above.

understanding "in accordance" with a statement by the International Chamber of Commerce (ICC) (no. 64). The companies thereby introduced ambiguity, because the ICC did not commit itself to the normative statement that there is inequity in the IPR system, but merely to the empirical statement that there is widespread perception of inequity (no. 64, footnote 25, excerpt). So it remains unclear whether these companies really acknowledged injustice or just the perception of injustice.

Built-in ambiguities may be a necessary price for a consensus document in contested areas. Another such price seems to be that the Final Report is silent about the reasons why the lack of protection of TK constitutes injustice. The participants may have agreed that the relations between the traditional and the modern parts of the world are "essentially unjust" (no. 75), but whether this injustice be addressed through the protection of TK rather than by means of other instruments such as special funds a is different question. One cannot assume that all participants embraced the notion that indigenous communities have inalienable human rights to exert unlimited control over their collective knowledge. In modern societies knowledge which has been disclosed in the past—also the "traditional" knowledge from local cultures of farmers and craftsmen—can be freely used and circulated (including to indigenous communities) without consent or compensation, and no human rights objections are raised.

One reason why TK from indigenous communities should be specifically protected—a reason that both sides may have shared—was stated in the discussion: In modern sectors, original inventors or holders of "traditional" knowledge need no protection, because they are included in the flow of indirect benefits that come from the free use of their knowledge—that is, benefits in terms of new products (e.g., medicines), new technology, and economic growth. In accord with this argument, therefore, holders of TK in indigenous communities would require special protection of their knowledge, because they are largely excluded from any benefits to be derived from unrestricted use of TK outside the community.⁷

4.3. Against "Biopiracy"

There was a clear consensus that companies should under no circumstances try to obtain patents on the TK accumulated in indigenous communities without consent, nor seek access to such knowledge by "breaking" into the cultural space of these communities (nos. 88, 89). Without going into the details of the argumenta-

A similar argument could, in principle, also be made for disadvantaged groups or cultures within the modern sectors. Anil Gupta, for example, advocates special IP protection schemes for inventions in local cultures or at grassroots level in modern societies. See Gupta, A., "IP for Traditional Knowledge Online: Recognizing, Respecting and Rewarding Creativity and Innovation at Grass Roots", downloadable at http://ecommerce.wipo.int/meetings/2001/conference/presentations/pdf/gupta.pdf. The participants of the Dialogue were aware of these proposals. However, they confined deliberations to the problems confronted by indigenous communities.

tion, the participants also agreed that TK should constitute "prior art"—thus excluding patenting—and that documentation of prior informed consent should become a prerequisite for the patenting of inventions based upon TK (no. 89). The text leaves it open, whether the stipulation to indicate prior informed consent is to be seen as a material precondition for the granting of patents or, rather, as a technical criterion such as the payment of patent fees or the best-mode requirement.

Consensus on these conclusions was easily achieved, because they are equally defensible under diverging cultural and legal perspectives. From an indigenous community perspective, these conclusions (nos. 88, 89) follow from the recognition that those communities have an inalienable right to ownership of their collective knowledge. From a modern society perspective, they follow from established principles of patent law and trade secret protection.

The participants implicitly agreed that, as a rule, companies would have to negotiate with indigenous communities in order to gain legitimate access to TK and to avoid the risks of "biopiracy". A framework of negotiation provides options for taking the concerns and interests of the communities into account.

4.4. Flexibilities Within the Contract Framework

There was considerable common ground regarding the rules that should apply when companies seek access to TK that is not generally known but must be disclosed by indigenous communities. The Dialogue participants agreed that companies must accept that the indigenous communities have full control over the knowledge they disclose and that companies cannot use, disseminate, or obtain IPRs for that knowledge without the free and informed consent of the communities and without benefit sharing as stipulated by the communities (nos. 85, 86, 89, 97).

Such rules, no doubt, resonate with demands raised by indigenous communities. They can, however, partly be read as applications of basic principles of fairness that hold for any contract relationship. Mutual respect and recognition of the partners as equals are, in fact, implied in the very idea of a contract. To that extent, it is a self-evident duty, and not a concession, that companies accept that indigenous communities can freely decide under which terms they would be willing to strike a deal.

The important point is that these rules recognize and strengthen the autonomy and self-determination of indigenous communities by installing them as the relevant partners in the first place. The rules are designed to exclude any attempt to bypass the indigenous communities and deal with national authorities alone, who claim to have a mandate to manage TK on behalf of those communities.

The participants of the Dialogue included more proposals of how companies could (and should) use the flexible options that the contract paradigm offers, in order to be responsive to the specific needs and demands of indigenous communities. The participants advocated that the endless discussions over who is the legitimate holder of the knowledge be cut short, by giving the benefit of doubt to communities who present themselves as the holders of knowledge to be disclosed (nos. 93-96). Furthermore, they urged companies to accept that local rules and customary law apply in the interaction with indigenous communities (nos. 82, 92). Application of customary law is not simply one further precondition that the communities can stipulate for the negotiation; it is, at the same time, a mechanism to control the impact of the obvious inequality in bargaining power between the partners of the contract. In view of this inequality the Dialogue underlined the need for companies to undertake measures to build trust and to contribute to capacity building of the indigenous communities (nos. 84, 91).

It was also accepted that benefit sharing arrangements could be used to commit companies to contributions that support the broader social and political concerns of the indigenous communities (nos. 97, 99). And, in line with the institutional philosophy of the World Business Council, a cautious proposal was included that encourages companies to accept some political responsibility for the improvement of North-South-relationships and the development of indigenous communities, and to consider benefit sharing beyond the limits warranted by a purely financial assessment of the value of the knowledge disclosed (no. 98).

4.5. The Other Side of the Coin: Exit Options in Negotiations

The rules defined in the Dialogue for negotiations between indigenous communities and companies may well provide some models for an equitable sui generis scheme for the protection of TK; but, they are rules for contracts. The willingness of companies to accept that customary laws be applied and a broad range of benefit sharing be considered, when they negotiate with indigenous communities, may well have been contingent upon the fact that companies have an exit option. They can decide to abstain from a deal if they consider the price or the transaction costs to be too high, if they find better alternatives, or if compliance with the demands of the indigenous communities would bring the companies into conflict with national governments (see nos. 95-99).

Companies can legitimately assess only the economic gain they expect from the use of TK; they can ignore the cultural value their indigenous partners attach to this knowledge. Indigenous communities, in contrast, can also use the exit option to defend their specific visions of cultural value, for instance, as a means to refuse the patenting of TK, or to prevent the commercial use of "sacred" knowledge.8

4.6. Collision of the Customary and National Legal Systems: TK in the "Public Domain"

The real test of how diverging cultures can be accommodated comes with the rules for their interaction outside contractual relationships. How is TK demarcated? Are there cases where TK can be used without infringing upon the rights of indigenous holders, and hence without the need to negotiate? Should the answer to these questions be drawn from the customary law of the indigenous community or from the legal system of modern societies? The participants in the Dialogue discussed the contested issue of whether TK that has been disseminated and published outside the indigenous community should no longer be protected because it would then, in modern terms, be in the "public domain".

The legal systems collide over this issue. Some indigenous perspectives portray the ownership of TK as an ancestral natural and inalienable right of the community, which can only be recognized but not (rightfully) changed by the national legal system. Accordingly, indigenous representatives and associated NGOs rejected the concept of "public domain" as purely Western.⁹ From the national perspective, the concept of sovereignty implies that the states define the collision rules for the interaction of cultures within their territory. The question can only be whether the public domain (and free accessibility) status should be restricted in the case of TK through national (or international) law.

The participants proposed to uphold the public domain principle with some modifications (nos. 103-106): TK should only be in the public domain if it has been disclosed through mass communication; publication in ethno-scientific journals should not count as sufficient disclosure. These proposals tend towards modern legal concepts. Probably all the participants could in the end "live" with them, because the proposals reflect the fact that cultural diffusion is inevitable. Knowledge "travels". That cultural diffusion is not a one-way street from the modern to the indigenous community, but that it also goes from the indigenous community to the modern society, can be read as a sign that TK is viable and strong, and that indigenous communities are not isolated islands, but evolving and interacting social systems.

⁸ Another example was reported by an indigenous participant in the Dialogue: His community is offering the use of some TK, which might lead to valuable new medicines, without any benefit sharing. However, the community will not accept the acquisition of patent protection for medicines derived from that

⁹ In cultural, not in geographical terms. The "public domain" concept holds as well in the modern legal systems of societies in the South.

4.7. Changing Concepts of "Sacred" Knowledge

The diffusion of TK was also recognized in the rules proposed for "sacred knowledge" (no. 107). The participants confirmed the rights of indigenous communities to object to any use of TK that violates their notions of "sacredness". But they also acknowledged that the knowledge comes under different cultural frames if it "travels"—be it to other indigenous communities or to the modern sectors of national societies. Thus, traditional medicines, which may have been deeply embedded in religious ritual in their communities of origin, may become disembedded and treated as purely instrumental, once they have been integrated into the "alternative medicine" complex of modern health systems. Such cultural shifts cannot be opposed on the ground that they violate the values of the original community. Respect for the integrity of cultures requires that no community impose its cultural values on other communities. Indigenous communities would certainly admit this in relation to other indigenous communities; but there is no reason why, if this principle is applied consistently, that it should not also hold for the relationship to the modern sectors of the society.

4.8. Should the Rights of the Holders of TK Ever Expire?

Ownership of TK is often portrayed as an ancestral collective right that is transferred from generation to generation and will not end as long as the community holding the knowledge persists. The notion that the protection of TK should last for ever collides with modern concepts of IPRs. These concepts condone temporally unlimited rights to authorship and names, but not to exclusive rights to the use of knowledge. Modern IPRs that grant "ownership" of knowledge have time limits. The only exceptions are trade secrets, which last as long as they can be upheld.

Sui generis regimes for the protection of TK will have to resolve this conflict of legal concepts. The Final Report points toward a solution modeled on the protection of trade secrets. Protection should last as long as efforts are made (presumably successfully) to keep the TK confidential within the community that holds it (no. 113).

4.9. Differentiation Within Indigenous Communities: Can TK Be Obtained Legitimately From the Traditional Healer?

The image of indigenous communities relevant in debates over the protection of TK is often one of homogeneous groups acting in solidarity. Real communities, however, may be rife with inequalities and conflict over status and power—just as any other society. The participants of the Dialogue were confronted with this issue when an African healer argued that healers have individual rights as creators and

innovators of TK, which, in turn, must be balanced with the collective rights of communities as the custodians of TK.

The Final Report acknowledges the individual rights of the inventors of TK (no. 67), but it seems to presuppose that the inventors (i.e., the healers) are firmly integrated into the indigenous community. In this case, possible conflicts of interests and rights would have to be resolved by recourse to the customary law of the community. Moreover, companies who seek access to the TK of the healer would clearly have to address the community as well.

More difficult questions arise when healers are organized in national associations, as they are in some African countries. Such associations resemble more professional bodies than institutions of indigenous communities. They constitute bridges to the "outside world" and illustrate how indigenous communities are embedded in and diffuse into the modern sectors of the national society. The Dialogue did not address the issue of which rules should apply when TK is managed and developed by organized healers; nor did it consider in which cases companies who want to use the knowledge of the healers must also contact the indigenous communities to gain legitimate access.

4.10. TK of Migrants to the Modern Sector

A related question is whether indigenous people who migrate to the modern sectors of the society can continue to benefit from the TK they hold. Such migration is common, and it is a right indigenous people enjoy as national citizens — even when it is viewed as "defection" from the perspective of the indigenous home community. It is hard to imagine that, under the national legal system, migrants should or would lose all rights to use the skills and competences that they acquired during socialization, simply because they move from village to town or because the customary law of their former village declares these skills and competences to be the collective property of the community.

A different matter is whether the migrants should also have the right to proliferate their TK or sell it to third parties. It was a common understanding among the participants in the Dialogue that companies should not seek access to TK from individuals in the modern sector without the consent of the communities who are the original holders—at least not as long as the communities try to keep the knowledge confidential (nos. 82, 93, 113).

4.11. The Scope of Cooperation in the Dialogue

The Dialogue procedure induced cooperation between companies and representatives of indigenous communities (and the NGOs supporting them) in the search for "best practice" rules concerning how TK could be used legitimately for commercial purposes. The parties underlined the fact that, in the absence of an

accepted legal framework for the protection of TK, goodwill must be exercised by the parties concerned to build trust, and latitude must be provided for experimentation (nos. 79, 87, 90). The participants managed to propose a set of rules, which they understood as conditions for a proper regime of TK, based on mutual respect and recognition between the holders and the potential users of the TK.

What the Dialogue did not achieve was a commitment on the part of the indigenous representatives and the associated NGOs that they would defend companies against further moral attacks and accusations of "biopiracy", if the companies fully complied with the rules proposed in this Dialogue. Obviously, the companies would have appreciated such a commitment, but it appears unrealistic to assume that representatives of indigenous communities and NGOs would have a mandate to sign a "treaty" defending companies against public criticism.

In addition, in view of the broader political concerns that the indigenous communities have on their agendas, nothing that can be achieved within the narrow confines of the Dialogue will really be satisfying. Accordingly, there is a tendency in the public debates to "shift the goalposts" and escalate demands. Although this tendency was absent during the Dialogue, the representatives of indigenous communities and NGOs are nevertheless likely to be confronted with it in their constituencies outside the Dialogue. This limited what the representatives from the indigenous communities and NGOs could accept or at least let pass as proposals for the Final Report.¹⁰

Limited cooperation is all one can expect from a stakeholder dialogue in a contested political field. Nevertheless, the fact that there has been cooperation with indigenous representatives and their associates in devising the rules for company behavior sends an important signal to the public. That signal will mitigate future conflicts, if companies comply with the rules adopted.

4.12. Trade-off: Optimizing the Protection of TK Versus Using TK?

The Dialogue proceeded from the assumption that win-win situations must be constructed, in which indigenous holders of TK are equal partners and have their rights recognized in the interaction with companies who pursue the commercial use of TK. This assumption implies that one does not hold the position (a) that segregation is better than interaction and (b) that expounding public conflicts to transnational companies is more instrumental to indigenous objectives than negotiating contracts. It also implies that one must not increase the transaction costs to a degree that makes contracts unattractive.

¹⁰ One representative of an NGO that strongly advocates indigenous community concerns did not want to sign the Final Report as a participant, and asked to be listed as observer.

There were warnings from some participants—not only from industry—that optimizing the protection of TK should not lead to rules so complicated that the use of TK is not a viable option for companies. TK would then become obsolete as a resource of benefits to be shared with the communities holding the knowledge. One African representative held that the risk that TK will be neglected was greater than the risk that it will be misappropriated. The risk of neglect may be aggravated by the fact that pharmaceutical companies rely increasingly on science-based, reductionist drug development strategies, which allegedly can do without the information provided through TK.

Whether, in fact, the rules envisaged in the Final Report would actually preclude the commercial use of TK must be tested. The participants in the Dialogue would no doubt want that this test is made.

Appendix

IPR Dialogue Process — 4th CIRCULAR

Survey of Arguments in Working Group II: Protection of Traditional Knowledge (PTK)

APPENDIX: "4th Circular"



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IPR Dialogue Process — 4th CIRCULAR Survey of Arguments in Working Group II: **Protection of Traditional Knowledge (PTK)**

Dear Participant,

As you may still remember, the Montreux Working Group II on the Protection of Traditional Knowledge (PTK) had summarised its discussions in a set of statements and topics which were presented at the plenary session. The following table recalls this summary.

Results presented by Working Group II at Montreux

Issues	- Do not ignore parallels to other processes (e.g.: Crucible Group)			
	- Try to use recommendations developed in other contexts			
	- Integration of indigenous groups			
	- Prevention of "Biopiracy"			
	- Access to TK should not be barred			
	- Generosity of poor holders of knowledge must be honoured			
	- Knowledge/person of traditional healer should be acknowledged			
	- Make sure that IPRs do not harm TK			
	- Acknowledge the holistic system underlying TK			
	- TK cannot be separated from rights to land/cultural rights			
	- TK should be supported			
	- The real issue is equity			
	- Inherent unfairness in the intellectual property system			
Recommenda-	- Declaration of origin of material/TK			
tions	- Capacity-building with regard to holders of TK			
	- Capacity-building with regard to the non-granting of patents (for instance in cases of contradiction with the CBD)			
	- TK certification/labelling			
	- Benefit sharing: contribution to a fund which can be used to sustain TK			
	- Foster win/win-situations			
	- Prevent abuses of rights			
	- Modify existing IP instruments			
	- Create new IP instruments			
	- Application for appropriate IP protection			
	- Industry should be responsible for shaping adequate IP systems			

Proposed Activities	- Systematic study on TK (which is used, appropriated, in public domain, misappropriated?)
	- Develop guidelines for socially responsible partnerships (disclosure of origin, capacity-building, forms of BS: monetary, non-monetary)
	- Summarise and elaborate on successful private-public partnerships (try to further develop them in line with the guidelines)
	 Develop elements of an International Treaty on Innovation, fully integrating the broader concepts of TK
	- Integrate the recommendations into business strategies.

The discussions in Montreux barely tackled the broader political, legal and cultural issues that are in many ways underlying the debates over PTK — such as protection of indigenous cultures and communities at large, land distribution, or recognition of indigenous/local communities by national governments. These broader issues are clearly of importance for the struggle of indigenous people for self-determination and the improvement in their livelihoods. And the participants were, of course, aware of these issues. They nevertheless focused their discussions mainly on IP or Non-IP-related aspects of how to protect indigenous/traditional knowledge.

We propose to follow the same line and keep that focus, as well as the emphasis on intangible assets. On the other hand, one must not loose sight of the broader background issues. The following table gives an overview:

Issues in the Protection of Traditional Knowledge

Political recognition of the holders of TK (indigenous knowledge)	Threats to the main- tenance of traditional knowledge/indigenous knowledge	Protection of traditional knowledge/indigenous knowledge	IP Protection of traditional knowledge/indigenous knowledge
Struggle for political self-determination; Unjust land distribution systems; Maintaining the livelihoods; Acknowledgement of practices/achievements TK/IK holders	"Biopiracy"; suppression of indigenous peoples; lacking incentives for the protection of TK/IK; cultural/demographic factors; inappropriate land use/conservation systems	Maintaining life support systems; economic income; sustainability; local health care systems; Mechanisms for the protection of TK/IK	Rendering the IP system fairer and more equitable Public/private controversy Individual rights/collective rights

In the attached file "Argumentation PTK (long version)" we have complemented the contributions from participants in Montreux by statements from various documents (listed in the appendix to the long version file) to cover the whole range of the above issues. The arguments are presented under the following headings:

- 1. Definition of TK
- 2. The value of TK
 - a. General value and value for the indigenous community
 - b. Commercial value

- 3. Objectives of PTK
 - a. Protecting the traditional/indigenous community
 - b. Recognition of TK as a knowledge system
 - c. Recognition of the right to control the use of TK
 - d. Fairness and justice entitlements to compensation and sharing benefits from the use of TK
- 4. The mandate of the nation state and the rights of the holders of TK
- 5. TK in the public domain
- 6. Rules and mechanisms: Non-IP instruments for PTK
- 7. Rules and mechanisms: IP instruments for PTK
- 8. Expectations from/recommendations to the WBCSD

We do not provide a specific "condensed version" from these arguments in this CIRCULAR. We indicate instead below main points that emerged in the Montreux discussions. We propose to start further discussions from those points. They are presented in detail in sections 6 and 7 of the file "Argumentations PTK (long version)".

We add some questions that go a little bit further. We kindly ask the participants to reply to these questions and thus stimulate further deliberation. The questions echo to a certain extent the programme for a small session we are organizing in October in Bonn. That session makes use of the opportunity of the CBD ad hoc working group meeting on access and benefit sharing. It will bring together a number of participants of the PTK working group of our dialogue process — some of whom will come to Bonn anyhow. The preliminary programme is in the attachment. Whatever will be discussed in the Bonn meeting, will be reported for comment to all participants in due time.

Summary of Points raised by the Participants of Working Group II (PTK) in Montreux

Protective measures outside the IP system (see section 6 of long version file)

- certification
- guidelines for socially responsible investment
- new international treaty on innovations
- protect healers and communities by national law
- national gene funds (for benefit sharing purposes)
- national registers for traditional knowledge

Protective measures within the IP system (see section 7 of long version file)

- modify the existing IP instruments in order to render tem suitable to an application to traditional knowledge (longer grace periods, first-to-invent principle)
- create a new sui generis IP system specially shaped for the protection of traditional knowledge
- self-commitment on the part of the companies not to exert political pressure on governments to implement TRIPS plus treaties
- self-commitment on the part of the companies not to prevent member states from using the leeway and flexibility provided for under the present TRIPS agreement
- capacity building not to grant patents in those cases where this would clearly contradict other legally binding agreements

- reduce costs for obtaining IP protection
- link declaration of origin, prior informed consent and benefit sharing agreements with the IP-granting mechanisms

Expectations from/recommendations to the WBCSD (see section 8 of long version file)

- provide genuine partnerships of equal players (bio-partnerships)
- capacity-building for negotiators
- roundtable on IPRs
- setting of common standards for the procedure of exchanging knowledge and materials
- develop a protocol on the use of pre-existing knowledge (public domain)
- explore the certification idea
- common monitoring of biopiracy
- getting help in rejecting predatory patents
- new international treaty on innovations

Further Questions

Question No. 1:

The problem was raised how not only communal traditions and practices can be acknowledged but also individual achievements generated by single healers. Does this question indicate that differentiations within indigenous/traditional communities (differences in interests and positions) must be more carefully taken into account in a system for the protection of TK? How should individual and collective IPRs and use rights be balanced for members of indigenous communities?

Question No. 2:

Should those segments of knowledge which are — from a western point of view — in the public domain be redefined as protected subject matter in order to serve the concerns and interests of traditional/indigenous communities?

- a) To which knowledge segments should such an approach apply?
- b) Is such an approach feasible?
- c) Is such an approach desirable?

Ouestion No. 3:

IPRs are usually granted for a limited time period (e.g., 20 years). Is the rationale for such a limitation applicable to TK? What would be a proper time frame (retrospective and prospective) for rights to TK?

Further Questions, Remarks, etc.?

These questions are also included in the e-mail to which this CIRCULAR is attached. Please use the reply function to send your responses by e-mail.

With best regards from the WZB team,

Achim Seiler

IPR Dialogue Working Group II (PTK)

Argumentation: "Protection of Traditional Knowledge (PTK)" (long version)

List of Topics:

The arguments presented here include the contributions from the participants in Montreux and, in addition, statements from various documents (listed in the appendix). The topics cover a broad range of issues raised in the context of PTK. They can be arranged under the following headings:

- 1. Definition of TK
- 2 The value of TK

General value and value for the indigenous community

Commercial value

3. Objectives of PTK

Protecting the traditional/indigenous community

Recognition of TK as a knowledge system

Recognition of the right to control the use of TK

Fairness and justice- entitlements to compensation and sharing benefits from the use of TK

- 4. The mandate of the nation state and the rights of the holders of TK
- 5. TK in the public domain
- 6. Rules and mechanisms: Non-IP instruments for PTK
- 7. Rules and mechanisms: IP instruments for PTK
- 8. Expectations from/recommendations to the WBCSD

The focus of the Montreux discussions in the Working Group had been on the topics in section 6 and seven (in bold). We propose to keep that focus and include topic 5 (TK in the public domain) in the deliberation. We have given the arguments under these topics number so that you can easily refer to them.

1. The Definition of TK

The following statements indicate the range of the debate and the demarcation of traditional knowledge. The working group proceeded from the implicit assumption that it is not necessary to clarify issues of demarcation for the purpose of their discussions. We propose to accept this.

- There is no agreed definition of traditional knowledge (1:3)
- Indigenous knowledge is a subset of TK which is no different except that the holders are indigenous peoples rather than non-indigenous communities embodying traditional lifestyles (J. Mugabe, ACTS)
- unwritten corpus of long-standing customs, beliefs, rituals and practices that have been handed down from previous generations (J. Mugabe, ACTS)
- Traditional knowledge is generally expressed in the communities and encompasses expressions of folklore, religion (e.g., sacred places, plants, animals), crafts (e.g., developments of technologies for producing textiles, food), agriculture (e.g., management of

- ecosystems, development of plants and animals with specific properties), and medicines (e.g., herbal products). (2:3)
- knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity (CBD, Art. 8j)
- indigenous knowledge, cultures and traditional practices (preamble, Draft UN Declaration on the Rights of Indigenous Peoples)
- WIPO acknowledges the right of indigenous groups, local communities and other TK holders to decide what constitutes their own knowledge, innovation, cultures and practices, and the ways in which they should be defined (3:4)
- For purposes of its work in this area, WIPO uses the term "traditional knowledge" to refer to tradition-based literary, artistic or scientific works, performances, inventions, scientific discoveries, designs, marks, names and symbols, undisclosed information, and all other tradition-based innovations and creations resulting from intellectual activity in the industrial, scientific, literary or artistic fields (3:4)
- Categories of traditional knowledge include: agricultural knowledge, scientific knowledge, technical knowledge, ecological knowledge, medicinal knowledge, including related medicines and remedies, biodiversity-related knowledge, expressions of folklore in the form of music, dance, song, handicrafts, designs, stories and artworks, elements of languages, such as names, geographical indications and symbols, and, movable cultural properties (3:4)
- Traditional resources are meant to include tangible and intangible assets and attributes deemed to be of value (spiritual, aesthetic, cultural, economic) to indigenous and local communities. Resources describe all that sustain communal identity, express history, are manifest in nature and life, sustain the pride of unique heritage, maintain a healthy environment and from which emerge sacred and spiritual values (5:15)
- Draft Article 15.2 (a) of the revised International Undertaking requires measures for the protection of "traditional knowledge", but, in view of the scope and purpose of the Undertaking, it only refers to knowledge "relevant to plant genetic resources for food and agriculture". Art. 15.2 is, thus, narrower in scope than Article 8 (j) of the CBD, and would not apply, for instance, to knowledge relating to medicinal or industrial uses of plant genetic resources. Under this approach, the issue of protection of traditional knowledge may be circumscribed to knowledge incorporated in farmers' varieties ("landraces") and certain associated knowledge (e.g., specific cultivation practices). (8:35)

2. The Value of TK

a. General Value and Value for the Indigenous Community

- Modern agricultural practices depend upon crop species with characteristics of productivity and disease resistance that can only be maintained and improved with the continuous input of new germplasm. Most of this germplasm comes from landraces (or folk varieties) bred and conserved by traditional communities over millennia (4:34)
- TK systems are increasingly accepted as an important source of useful information in the achievement of sustainable development. Studies of local communities provide evidence that the protection of TK can provide significant environmental benefits ... (3:6)
- TK is valuable first and foremost to indigenous and local communities who depend upon TK for their livelihoods and well-being as well as for enabling them to sustainably manage and exploit their local ecosystems such as through sustainable low-input agriculture (1:5)

- For those comprising the poorest segments of developing country societies, traditional knowledge is indispensable for survival (UNCTAD 2000)
- Much of the world's crop diversity is in the custody of farmers who follow age-old farming and land-use practices that can conserve biodiversity and provide other local benefits, such as diet diversity, income generation, production stability, minimization of risks, reduced insect and disease incidence, efficient use of labor, intensification of production with limited resources and maximization of returns with low levels of technology (3:6)
- It has been argued that biodiversity, and the traditional knowledge associated with using it in a sustainable manner, are a comparative advantage of those countries that are biodiversity-rich, enabling them to participate more effectively in global markets and thus rise above current levels of poverty and deprivation (3:7)
- Indigenous peoples feel they need more political and financial support to strengthen and defend their beleaguered cultures and communities. They also feel they need additional legal protection against uninvited and unwanted exploitation of their knowledge and resources. And, when they do authorize the use and application of their knowledge, innovations and practices, they want legal assurances that they will receive just compensation and equitable benefits from such use (5:1)
- It is estimated that over one-third of the world's population lacks regular access to affordable essential drugs. For these people, modern medicine is never likely to be a realistic treatment option. In contrast, traditional medicine is widely available and affordable, even in remote areas, and generally accessible to most people (6:2)
- With the widespread use of traditional medicine and the tremendous expansion of international herbal products markets, the great commercial profit from traditional medicines and medicinal plants have also brought serious problems of biodiversity loss (6:3)
- There is increasing recognition that the wider use and application of traditional ecological knowledge, as well as local or indigenous natural resource management systems, provide effective alternative strategies for conservation and sustainable use of natural resources. As a result, environmental concerns increasingly focus on the roles of indigenous peoples and local communities in enhancing and maintaining biological diversity (5: xiii)
- RAFI estimates (...) that "80% of the world's people continue to rely upon indigenous knowledge for their medicinal needs and possibly two thirds of the world's people cannot survive without the foods provided through indigenous knowledge of plants, animals, insects, microbes and farming systems ..." (7:0)
- The (indigenous) knowledge and innovation system is vitally necessary, not to replace the "institutional innovation system" that dominates modern science, but to complement it. The institutional system tends to produce highly specific "micro" improvements that then have broad applications in such fields as molecular biology or micro-electronics. The cooperative system, on the other hand, tends to produce macro-system innovations that can only be applied at the local level (for example, because they involve a complex mix of plants, insects and soil) (7:0)
- Contrary to widespread belief, indigenous knowledge is not the passive, accidental accumulation of information about how the natural environment works. Rather, it is an organized, dynamic system of investigation and discovery that has yielded and continues to yield information that could be critical to the survival of the planet (7:0)

b. Commercial Value of TK

- It has been argued that biodiversity, and the traditional knowledge associated with using it in a sustainable manner, are a comparative advantage of those countries that are biodiversity-rich, enabling them to participate more effectively in global markets and thus rise above current levels of poverty and deprivation (3:7)

- The possibility of future drugs based on traditional plant remedies is in large part rooted in the fact that historical examples exist: aspirin, antibiotics, and quinine only a few of the more common. However, it is not at all clear that the future of pharmaceuticals will depend on bioprospecting activities nor the input of traditional medical knowledge (11.3)
- Several ethnobotanists and others have routinely overestimated the economic potential of pharmaceutical bioprospecting by failing to account for R&D costs, alternative approaches to drug R&D now preferred by pharmaceutical companies, and the enormous quantity of biological samples necessary to find promising leads (11.4)
- While many have commented on the resurgence of bioprospecting activities among pharmaceutical companies in the 1990's it is also clear that such activities are once again on the decline. This is in part due to the politicized atmosphere created by the Convention on Biological Diversity and the accompanying mobilization over other nations' rights to biological patrimony and indigenous/local groups traditional knowledge (11:4)
- It seems to me that there are actually some very basic uncertainties here and we don't seem to quite know who the players are, even; there seem to be some kind of different views about this, and a certain amount of confusion jumps that we have been encountering: is it the universities who do want to use traditional knowledge, is it the pharmaceutical companies, or is it not the pharmaceutical companies ... It makes me wonder what we can get pharmaceutical companies to commit ourselves to if they aren't even interested in traditional knowledge (Part Mon. WGII expert)
- Now that is something interesting that a lot of work has been done but it is not being done at this moment from the intellectual property activity, at least, if you took that as a signal, it is not being done on plants which have not yet been discovered, unknown or obscure, these are generally plants very well known on which details exist, which essentially means that perhaps companies that are trying to use the public domain biodiversity knowledge and trying to sharpen their research in terms of finding out molecules or their effective drugs or whatever else and thereby seeking intellectual property which is a very interesting trend compared to what it was earlier (participant Montreux WGII expert)
- Meters and meters of books which contain ethnobotanical studies and as far as I know the process in industry is first to go into these books to look what is worthwhile (participant Montreux, WG II observer)

3. Objectives of PTK

The objectives for the protection of traditional/indigenous knowledge vary widely. They range from the overall protection of the social and cultural communities from which the TK/IK emerges to the recognition of TK as a knowledge system, the rights of the holders of such knowledge, e.g., against appropriation from outside the community, and to issues of fairness and justice in benefit sharing.

a. Protecting the Traditional/Indigenous Community

- Bio-cultural space should be the basis of the protection (land rights, cultural rights, self determination), otherwise we loose the richness of the knowledge (part Mon WG II NGO)
- One point is that we want to prevent abuse. Another issue is that people having this knowledge have the autonomy to decide by themselves what is going to happen with this knowledge and finally it is important that this knowledge can live on, that the cultural entity and what engendered this knowledge is supported. (participant Montreux, WG II observer)
- Indigenous peoples feel they need more political and financial support to strengthen and defend their beleaguered cultures and communities. They also feel they need additional legal protection against uninvited and unwanted exploitation of their knowledge and resources. And, when they do authorize the use and application of their knowledge,

- innovations and practices, they want legal assurances that they will receive just compensation and equitable benefits from such use (5:1)
- Traditional knowledge has to be supported economically, e.g., by a juridical system otherwise it is not able to survive and the other economic tool is to create (specially shaped) intellectual property rights (participant Montreux, WG II observer)

b. Recognition of TK as a Knowledge System

- Contrary to widespread belief, indigenous knowledge is not the passive, accidental accumulation of information about how the natural environment works. Rather, it is an organized, dynamic system of investigation and discovery that has yielded and continues to yield information that could be critical to the survival of the planet (7:0)
- Indigenous peoples have been relegated to "exotic footnotes" in history by many scientific, academic and political writers, ignoring totally their major contributions to global food, medicine, philosophy, the arts, environmental management and biodiversity conservation. Likewise, many countries have marginalized, weakened or even annihilated indigenous populations in an effort to obtain their lands, territories, and resources (5:1)
- To an extent that would astonish Western scientists, indigenous people recognize and value the particular properties or certain soils. Community healers may not know the exact bacteria or fungi, but they know the anti-tumor, antibiotic and steroid characteristics of the soil they use to treat wounds and diseases. Yet when companies collect this information, developing countries are not compensated for either the material or the knowledge (7:0)
- While traditional (and marginalized) knowledge is a binding and preserving factor for marginalized communities its lack of recognition and associated income means that it is rapidly loosing its significance to communities and is simultaneously fading away due to the ever fewer young people that are prepared to follow traditional ways. The basic fact is that young people do not see traditional practices as desirable because they are marginalized. (8:80)

c. Recognition of Right to Control the Use of TK

- Indigenous communities no longer control the genetic material they need for their survival.
 Even when it comes from developing countries, genetic material is generally stored in developed countries and controlled by developed-country scientists. Nearly 70 percent of all seeds collected in developing countries is stored in industrialized countries or in IARCs; more than 85 percent of microbial collections (yeasts, fungi, bacteria) are stored in developed countries (7:0)
- People have to recognize that knowledge has its owner and that those owners should be recognized and compensated in some way, regardless if that knowledge is in the so-called public domain (participant Montreux, WG II NGO)
- We think user rights should be distinguished from ownership rights in this matter (participant Montreux, WG II expert)
- I tell you that when we have tried to file patents and license and so forth, this process really generates money for these people; it does make their roles more respectful (participant Montreux, WG II expert/NGO
- The indigenous people state that, whether it's commercial or non-commercial, they still have to have consent; that is basic; this is a basic human right (participant Montreux, WG II, NGO)
- In most situations, knowledge and traditional medicine is at times appropriated, adapted and patented by scientists and industry, for the most part from developed countries, with little or

no compensation for the custodians of this knowledge and without their prior informed consent (6:3)

- While traditional (and marginalized) knowledge is a binding and preserving factor for marginalized communities its lack of recognition and associated income means that it is rapidly loosing its significance to communities and is simultaneously fading away due to the ever fewer young people that are prepared to follow traditional ways. The basic fact is that young people do not see traditional practices as desirable because they are marginalized. (8:80)

d. Fairness and Justice— Entitlements to Compensation and Sharing Benefits from the use of TK

- Overcome global injustices, overcome the inherent injustice of the present IP system (Part Mon WG II expert)
- Unfortunately, farmers are seldom compensated for the commercial value of their seed varieties. This situation is made even worse when private companies invariably in industrial countries patent material derived wholly or in part from farmers' varieties. Developing country farmers then find themselves paying for the end-products of their own genius. This approach of adopting germ plasma that indigenous farmers have developed and enhanced without developing a research-alliance with these innovators and involving them in further development of the varieties is a lost opportunity for the world to benefit from both modern and indigenous knowledge (7:0)
- To an extent that would astonish Western scientists, indigenous people recognize and value the particular properties or certain soils. Community healers may not know the exact bacteria or fungi, but they know the anti-tumor, antibiotic and steroid characteristics of the soil they use to treat wounds and diseases. Yet when companies collect this information, developing countries are not compensated for either the material or the knowledge (7:0)
- As industrial countries try to extend their system of intellectual property protection to ever wider fields of innovation including chemical and pharmaceutical products and processes, microbial and plant and animal varieties increasing claims are being made that developed-country corporations are not being paid royalties on the products sold in developing countries. In fact, however, non-payment of royalties is most severe among companies using but not paying for developing country farmers' varieties and medicinal plants in the development of their products (7:0)
- Community should benefit even if it does not contribute DNA (participant; PCII1:1) (NGO/expert/southern industry)
- Benefits to community even if no additional infrastructure has been provided (participant, PCII1:2) (NGO/expert/southern industry)

4. The Mandate of the Nation State and the Rights of the Holders of TK

The tension between the rights of nation states and the rights and claims of indigenous communities intrigue the debates over the implementation of the CBD. While this tension cannot be ignored it has not been made a focus of discussions in the Working Group.

- In the CBD, access to and transfer of genetic resources and technologies (including indigenous and traditional technologies) are assumed to be basic rights of States. But Indigenous peoples consider this a problematic issue that must be negotiated with local communities, whose rights are enumerated by international agreements and laws to which these same states are parties (5:xiii)

- Recently, environment, trade and development debates have emerged without taking into account the many well-established human rights and cultural heritage instruments that must temper all aspects of international governance including environmental decision-making
- There is a danger that in the sudden flurry of interests in indigenous and traditional knowledge, economic, political and environmental interests will dominate, overshadowing the basic human, cultural and scientific rights that are already afforded to local and indigenous communities (5:Xiii)
- Although the (sovereign rights of states over their natural resources) merely reflect a wellestablished principle in international law, national sovereignty over genetic resources is a controversial issues for Indigenous people (5:5)
- Indigenous leaders maintain that (natural sovereignty over genetic resources) contradicts international human rights law that guarantees that "all people may, for their own ends, freely dispose of their natural wealth and resources. They are concerned that governments that have historically been responsible for marginalizing indigenous peoples may enact legislation to implement the CBD that could violate indigenous territorial integrity and resource rights (5:5)
- Emerging contradictions in the burgeoning indigenous political movement, the problematic of applying familiar concepts of informed consent in research involving significant cultural difference, and some ramifications of the privatisation of the so-called "traditional knowledge" (11.2)
- We have got into a lot of trouble with CBD, namely they do not recognize the fact that traditional medicine in Africa is a professional practice. Unlike in some other places where it could be totally owned by the community. (participant Montreux, WG II expert)
- National initiative for benefit sharing (national gene funds); provide reciprocity towards the communities (participant Montreux, WG II expert)
- Special rules should apply when indigenous communities are involved in research. The first and most important is that the indigenous communities have the ability and right to choose to be involved or not and their BS should be separate from the nation state or states in which they live (participant PCII3:2) (industry)
- How is community defined? (participant, PCII1:2) (NGO/expert/southern industry)
- The challenge is identifying the appropriate representation of indigenous communities that should be consulted for permission/negotiation and Benefit Sharing. In this case the definition of community becomes extremely critical to differentiate, i.e., an actual specific geographically precise community of a certain indigenous group versus the communities in general (participant, PCII3:2) (industry)
- I think we should adopt an expansive definition of indigenous peoples. There should be a set of regulations for such research that respects the cultures of the groups concerned. (participant, PCII4:2) (expert)

5. TK in the public domain

Definition of public domain	1. What is the traditional knowledge documented and published? At this moment there is no estimate, no systematic study of how much of traditional knowledge which is in public domain and which is not in public domain is being appropriated by the pharmaceutical sector; we have no clear empirical estimate of this in study of this kind (participant Montreux, WGII expert)	
	2. The chemical industry believes that it is necessary to create inventories of traditional knowledge in order to determine the part of the traditional knowledge in the public domain and list it together with the indication of how and when it was communicated, if available. (CEFIC)	
	3. In preparing such inventories, care should be taken to determine the extent to which the traditional knowledge was communicated to other groups or not (with or without a secrecy provision) (CEFIC)	4. Concept of public domain is a western concept (participant Montreux, WG II NGO)
Informed consent required?		5. People have to recognize that knowledge has it's owner and that those owners should be recognized and compensated in some way, regardless if that knowledge is in the so-called public domain (participant Montreux, WG II NGO)
	6. We think user rights should be distinguished from ownership rights in this matter (participant Montreux, WG II expert)	7. The indigenous people state that whether it's commercial or non-commercial they still have to have consent that is a basic human right (participant Montreux, WG II, NGO)
	8. Science and technology should not suffer by extremely restrictive conditions on all kinds of investigation in the nature (participant Montreux, WG II expert)	

6. Rules and mechanisms: Non-IP instruments for PTK

The need for new instruments	9. Existing intellectual property rights (IPRs) are wholly inadequate and inappropriate for [the protection of TK], and special alternative or sui generis systems need to be created instead (5:Xiii)	
	10. Creation of a non-IP sui generis approach to an all encompassing protection of the skills, innovations, practices of indigenous peoples (Posey/Dutfield/Grain)	11. the chemical industry believes that traditional knowledge would be best protected by a sui generis right to be created. However, there may be circumstances where protection through existing IP systems is possible and preferable (CEFIC)
CBD is not enough	12. The CBD does not provide specific mechanisms to protect the rights of indigenous peoples and local communities to their genetic materials, knowledge and technologies. Nor does it establish effective means to secure equitable benefit sharing from the wider use and application of these resources. Therefore, such mechanisms will have to be developed (5:Xiii)	
	13. Indigenous leaders are concerned that governments that have historically been responsible for marginalizing indigenous peoples may enact legislation to implement the CBD that could violate indigenous territorial integrity and resource rights (5:5)	
Registers, inventories	14. Establish national registers for traditional knowledge (Part Mon WG II expert)	
	15. Clearing houses at global, regional and national level need to be set up to provide easy, accessible and fair opportunities for the registered TK to be negotiated (participant Montreux, e-mail, expert)	

	16. The chemical industry believes that it is necessary to create inventories of traditional knowledge in order to "fixate" the memory and present day use of all kinds of knowledge and know how belonging to the different indigenous people and local communities in all regions of the world and relating to all fields of technologies. This will both assist in conserving this knowledge for future generations and provide a background on which further innovations may be documented. (CEFIC)	
	17. Determine the part of the traditional knowledge in the public domain and list it together with the indication of how and when it was communicated, if available (CEFIC)	
	18. In preparing such inventories, care should be taken to determine the extent to which the traditional knowledge was communicated to other groups or not (with or without a secrecy provision) (CEFIC)	
	19. It is important that in those inventories a distinction is made between the traditional knowledge having a technological character and that of a basically artistic character (CEFIC)	
Prior informed consent for the use of TK	20. Indigenous people state that whether [the use of TK] is commercial or non-commercial [there must be] consent this is a basic human right (participant Montreux, WG II)	
	21. In most situations, knowledge and traditional medicine is at times appropriated, adapted and patented by scientists and industry, for the most part from developed countries, with little or no compensation for the custodians of this knowledge and without their prior informed consent (6:3)	
	22. One point is that we want to prevent abuse. Another issue is that people having this knowledge have the autonomy to decide by themselves what is going to happen with this knowledge. (participant Montreux, WG II observer)	

Certification of bioprospecting	23. [One could establish] certification in bio-prospecting, i.e., oversight of the activities by a second party (participant Montreux, WG II)	24. [Distinguish] There is the labelling question on the side of TK, which could then have a marketing advantage. The other side is to integrate the certification in the auditing systems which are anyway made in European and America industries (participant Montreux, WG II observer)
	25. academics benefit commercially they get PhD's etc [perhaps one should] certify academic behaviour, too (participant Montreux, WG II industry)	
Benefit sharing (BS) Communities entitled	26. If the state or an agency of the state is the custodian of the () medical information, a commercial organisation would probably expect to have to pay for access. It is matter for the state and the individuals who sources the samples and information to decide what BS should be, if any (participant, PCII2:2) (industry)	27. Special rules should apply when indigenous communities are involved in research. The first and most important is that the indigenous communities have the ability and right to choose to be involved or not and their BS should be separate from the nation state or states in which they live (participant PCII3:2) (industry)
	28. Benefit sharing agreements should reflect ownership mix (participant Montreux, WG II expert)	29. include benefits to nation (State) (participant, PCII1:2) (NGO/expert/southern industry)
	30. National initiative for benefit sharing (national gene funds); provide reciprocity towards the communities (participant Montreux, WG II expert)	
	31. The community should benefit [for participation in genetic research] even if it does not contribute DNA (participant; PCII1:1) (NGO/expert/southern industry)	32. Indigenous peoples should not receive more benefits because they are indigenous (participant, PCII4:2) (expert)
	33. Benefits should go to the community even if no additional infrastructure [for doing genetic research] has been provided (participant, PCII1:2) (NGO/expert/southern industry)	34. The same rules should apply to all peoples (participant, PCII2:2) (industry)
Non-commercial research	35. Academics [too] benefit commercially maybe one way [to share these benefits] is that every research expedition sets aside a percentage of [the research budget] to go back to the tribe (participant Montreux, WG II industry)	

Upfront payments	36. [There is] a potential conflict between the company's recognized obligations to local communities and the nature of the pharmaceutical industry. Although the needs of indigenous peoples are often urgent, development of a therapeutic agent generally requires a long lead-time, which can easily be a lengthy timeframe of five to ten years (10:7)	
	37. The company has been committed to the concept of reciprocal benefits, the terms of [which] are driven by the expressed needs of the peoples themselves: to developing new therapeutic agents by working with indigenous and local peoples of tropical forests, and, in the process, contributing to the conservation of biological and cultural diversity (10:7)	
Guidelines for BS	38. In the case of a developing nation or an indigenous people, where experience and trained individuals to lead a negotiation may not be available, guidelines as to what might constitute appropriate consideration for benefit sharing would be very useful (participant, PCII5:2)	39. It also seems that one ought to act or what a country wishes to do, rather on what some other outside group thinks th developing nation should undertake. Informed consent and benefit sharing ought to be defined in the context of a country's objectives, and not imposed from outside (participant, PCII5:2) (industry)
Research partnerships	40. Industry should be engaged in establishing bio-partnerships with indigenous communities and traditional healers in trying to protect intellectual property (participant Montreux, WG II expert)	
	41. We believe that indigenous people will gain more from building long-term strategic research partnerships with scientists and industry than for merely exercising the power to sell or withhold their knowledge (participant Montreux, WG II NGO)	
	42. Coalesce all players into one group (participant Montreux, WG II expert)	
Intermediaries	43. There are only few organizations, especially the universities and institutions like that, which can play an intermediary role (participant Montreux, WG II expert)	

Treaty on Innovation	44. I would like to see if industry would be interested with civil society and indigenous groups to call for a new international treaty on innovations; because obviously traditional knowledge has been left out (participant Montreux, WG II NGO)	
	45. I think a new treaty, a new rule of the game would be appropriate and then we can discuss about modifications of present IP instruments or the creation of new ones. (participant Montreux, WG II NGO)	
The need to safeguard access to TK	46. Clearing houses at global, regional and national level need to be set up to provide easy, accessible and fair opportunities for the registered TK to be negotiated (participant Montreux, e-mail, expert)	
	47. Science and technology should not suffer by extremely restrictive conditions on all kinds of investigation in the nature (participant Montreux, WG II expert)	
	48. The strictly bilateral approach to genetic resources/traditional knowledge should not hamper R & D; the transaction costs for bilateral Benefit Sharing mechanisms might be sometimes higher than the whole benefits to be distributed. In some cases a multilateral approach might be more advisable (participant Montreux, WG II observer)	

7. Rules and mechanisms: IP instruments for PTK

	49. TK has to be supported economically, e.g., by a juridical system otherwise it is not able to survive and the other economic tool is to create (specially shaped) intellectual property rights (participant Montreux, WG II observer)	
Are IPRs appropriate ?	50. IPRs should not be applied to traditional knowledge (participant Montreux, II NGO)	51. I tell you that when we have tried to file patents and license and so forth, this process really generates money for these people, it does make their roles more respectful (participant Montreux, WG II expert/NGO
		52. we made a small contribution to the Indians' legal battle in Lima and we feel that helps them, and so we could not have done that if we were not involved in a patent system where we were able to raise money (participant Montreux, WG II industry)
Protection of traditional healers		
Limits to the patent system Patent on sacred plants	54. The business sector [must] of understand that it is actually very bad for the image [to file a patent on sacred plants] we do not agree with this sort of behaviour and we won't have any part of that (participant Montreux, WG II expert)	
Patents on life	55. We differentiate patenting of life. Patenting a plant and patenting a biochemical from that plant are two totally different things. We are still totally opposed to a patenting of life but we have no problem whatsoever in somebody deriving a use from a plant (participant Montreux, WG II expert)	
Further policies	56. An interesting aspect is capacity building with our northern patent attorneys and lawyers not to grant patents in such cases where filing a patent would clearly contradict stipulations laid down in binding agreements such as the CBD. (participant Montreux, WG II observer)	

	57. I could imagine a self-commitment on the part of the industry not to exert political pressure on governments to implement Trips plus treaties, not to unnecessarily apply for product patents instead of process claims, not to prevent member states from using the leeway and flexibility provided for under the present TRIPS agreement (participant Montreux, WG II observer)	
Modified IPRs	58. There are many different IP instruments and the patent system is only one among them and there might be a potential to modify or at least apply those established IP instruments in a different way in order not to harm traditional knowledge or to develop entirely new systems. The question then would be who is the one to develop such an instrument and the second question would be what is the specific responsibility of the industry to foster win-win-situations using IP instruments (part Mon WG II observer)	
	59. The WBCSD who initiated this [stakeholder dialogue] process with a clear objective to implement what is called sustainability must clearly outline how sustainability with respect to very difficult issues like IPR questions can be operationalized (participant Montreux, WG II observer)	
Sui generis protection	60. WIPO has developed a model folkore law, folklore is entirely traditional knowledge and they had the first model law case. Most countries felt [at the WIPO meeting] that they are going into a new treaty for dealing with traditional knowledge (Part Mon. WG II expert)	
	61. The chemical industry believes that traditional knowledge would be best protected by a sui generis right to be created. However, there may be circumstances where protection through existing IP systems is possible and preferable. (CEFIC)	
Additional requirement for patents	62. Register traditional knowledge [in order to destroy novelty] (participant Montreux, WG II expert)	

Proof of legitimate access	63. Material [and TK] must have been acquired lawfully and rightfully [good ethical behaviour] (part Mon WG II expert	
Declaration of origin Informed consent BS	64. Declaration of origin, prior informed	
Grace period	65. Provide for a five year grace period so that communities who shared [material or TK] in good faith are not penalized (participant Montreux, e-mail, expert)	
First-to-invent protection	66. provide for a first-to-invent-protection system as in the US (participant Montreux, e-mail, expert)	
Costs of IPRs	67. The cost of seeking Intellectual Property protection by communities and individuals must be reduced. (participant Montreux, WG II expert)	
	68. We have considered to get the patents in the meantime [in our country] before things are patented over there But so far, we only obtained one patent. We have a patent which is owned by the association. But we have not done any further work because of the terrible costs involved. So we have, in a way, given up following this route because of the expenses involved (part Mon WG II expert)	

8. Expectations from/Recommendations to the WBCSD

- There are some requirements that countries have to do themselves. Some internal capacity building, some internal organizational framework before they can negotiate on that issue (participant Montreux, WG II expert)
- Provide genuine partnerships of equal players (participant Montreux, WG II expert)
- Capacity building for negotiation, because it's obviously extremely important to have a level-playing field and that is being discussed in many forums (participant Montreux, WG II expert/industry)
- There is no "THE" model. There are many different ways to do bioprospecting (participant Montreux, WG II NGO/industry)
- Round table on IPRs (participant Montreux, WG II expert)
- Dialogue on IPRs (participant Montreux, WG II expert)
- So we have a common cause. And that common cause with industry would be, first of all, how we set standards. I think that is one thing we could do together (participant Montreux, WG II, NGO)
- And those standards should be focused on the process, the procedure of exchanging this knowledge and materials (participant Montreux, WG II, NGO)
- The pre-existing knowledge and materials (public domain) require a protocol that should be recognized so that the use of those materials shouldn't affect the rightful ones (participant Montreux, WG II NGO)
- Explore the certification idea (participant Montreux, WG II NGO)
- Common monitoring of biopiracy (participant Montreux, WG II NGO)
- Getting help in rejecting predatory patents (participant Montreux, WG II NGO)
- New international treaty on innovations, where all types of knowledge and innovations can be brought together in a new arrangement (to be proposed at Rio + 10) (participant Montreux, WG II NGO)
- Make sure proposals and incentives are taken up by the companies and then turned into reality by incorporating them into the business strategies (participant Montreux, WG II industry)

Addendum: Survey of Literature Proposed by the Participants (Selection):

- CIEL: Biodiversity and Intellectual Property Rights, Geneva, 2001
- CEFIC: The Chemical Industry Comments on the Legal Protection of Traditional Knowledge and Access to Genetic Resources Patenting, 23 November 2000 (Brussels, mimeo)
- Chasek, P., et al.: Access to Genetic Resources: An Evaluation of the Development and Implementation of Recent Regulation and Access Agreements; Environmental Policy Studies No. 4, Columbia University School of International and Public Affairs, New York 1999
- Dutfield, G.: Intellectual Property Rights, Trade and Biodiversity, London 2000
- Greene, S.: Indigenous People Incorporated: A Case Study Approach to the Fight over Pharmaceutical Bioprospection, Traditional Knowledge and Intellectual Properties, University of Chicago 2001, (Chicago, mimeo)
- IUCN: Intellectual Property Rights A Battleground for Trade and Biodiversity? Gland 1999
- Kaubab, R., M. Broggio: CBD, TRIPS and the International Undertaking, Geneva 2000 (available from the South-Centre, Geneva)
- King, S., T. Carlson, K. Moran: Biological Diversity, Indigenous Knowledge, Drug Discovery, and Intellectual Property Rights, in: S. Brush, D. Stabinsky (eds.): Valuing Local Knowledge: Indigenous People and Intellectual Property Rights, Island Press 1996, pp. 167-185
- $Moran, \ K.: \ Lessons \ from \ Bioprospecting \ in \ India \ in \ Nigeria, \ available \ at \ http://www.cs.org/publications/CSQ/244/moran.htm$
- Posey, D., G. Dutfield: Beyond Intellectual Property, Ottawa 1996
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- Shiva, V.: Protecting our Biological and Intellectual Heritage in the Age of Biopiracy, New Delhi, 1996
- Ten Kate, K., S. Laird: the Commercial Use of Biotechnology, London 1999
- UNDP: Integrating Two Systems of Innovation, an Independent Study by the Rural Advancement Foundation International, New York 1996
- WIPO: Framing the Intellectual Property Needs and Expectations of Traditional Knowledge Holders, available at: http://www.wipo.int
- WTO: The Relationship Between the CBD and TRIPS with a Focus on Art. 27.3(b), Document IP/C/W/175, Geneva 2000