

World Business Council for Sustainable Development (WBCSD) (Ed.);
Wissenschaftszentrum Berlin für Sozialforschung - Social Science Research
Center Berlin (WZB) (Ed.)

Research Report

Intellectual Property Rights in Biotechnology and Health Care — Results of a Stakeholder Dialogue

Provided in Cooperation with:

WZB Berlin Social Science Center

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Intellectual Property Rights Investment

Innovation Technology Society Sustainability Nature Life

Property Rights **Biotechnology** Human genetic resources

Traditional knowledge Access to essential medicines in

developing countries Dialogue Civil society Patents Price

Research & Development Human rights Justice data Sam

Collection Control Storage Ethical Order Respect auton

Public Private Legal Protection Anti-discrimination Legi

Access to essential medicines in developing countries Co

Products Commercial Transparent Rules Law Trust Benef

Information Clinical trial Life science corporations Invest

Invention Moral Exclusive rights Open access Freedom R

Protect Licensing Biological Diversity Pharmaceuticals

Values Consent in **Biotechnology and Health Care**

Results of a stakeholder dialogue



World Business Council for
Sustainable Development

WZB

about the WBCSD

The World Business Council for Sustainable Development (WBCSD) is a coalition of 165 international companies united by a shared commitment to sustainable development via the three pillars of economic growth, ecological balance and social progress.

Our members are drawn from more than 35 countries and 20 major industrial sectors. We also benefit from a global network of 40 national and regional business councils and partner organizations involving some 1,000 business leaders.

Our mission

To provide business leadership as a catalyst for change toward sustainable development, and to promote the role of eco-efficiency, innovation and corporate social responsibility.

Our aims

Our objectives and strategic directions, based on this dedication, include:

- > **Business leadership** – to be the leading business advocate on issues connected with sustainable development
- > **Policy development** – to participate in policy development in order to create a framework that allows business to contribute effectively to sustainable development
- > **Best practice** – to demonstrate business progress in environmental and resource management and corporate social responsibility and to share leading-edge practices among our members
- > **Global outreach** – to contribute to a sustainable future for developing nations and nations in transition

about the WZB

The Wissenschaftszentrum Berlin für Sozialforschung (Social Science Research Center Berlin) is among the largest social science research institutes in Europe. It conducts research on developmental trends, problems of adaptation, and innovation in modern societies.

The stakeholder dialogue was organized and moderated by the WZB. A Steering Committee was set up to coordinate the work.

Steering Committee

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This report captures the views expressed by participants in the dialogue. Its content was managed by the Steering Committee.

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Executive summary

This report presents the results from a stakeholder dialogue launched by the WBCSD, which involved some 40 participants from major companies, non-governmental organizations, and legal and political experts in extended discussions over controversial issues of intellectual property rights in the application of modern biotechnology to medical R&D. The dialogue process was moderated by the Social Science Research Center Berlin (WZB). It took place from May 2001 to July 2002 and proceeded through face-to-face meetings and via internet exchanges, engaging participants in three topics:

- access to human genetic resources
- protection of traditional knowledge
- access to essential medicines

While the participants retained their diverging perspectives and concerns in many respects, they were nevertheless able to identify some common ground regarding the nature of the problems and possible options for dealing with them. The main emphasis was on what companies could do, and should do, within their corporate strategies to address these controversial issues.

Thus it was agreed that pharmaceutical companies when seeking access to human genetic resources should adhere to the highest standards of protection of human subjects and not exploit exemptions from the strict rules of informed consent. Companies should be able to receive samples and data from human subjects as a gift, but benefit sharing should be negotiated in research relations with subjects from developing countries and from indigenous communities.

The participants disagreed over the morality of patents on genes. However, they admitted that the moral views differ within the population at large. Therefore a general moral verdict is not warranted.

The scope of patents on genes was discussed at length. The participants emphasized the need to safeguard the necessary freedom-to-operate in R&D, also in developing countries. Some representatives from industry indicated that companies might be able to live with the more restrictive interpretations of patents on genes proposed in European legal debates; others disagreed. It was understood that many problems can be avoided through adequate licensing policies. The participants called for a more thorough empirical assessment of actual licensing practices and acknowledged the need to enhance good practice.

The participants accounted for the broader cultural and political concerns indigenous people consider as constitutive for the protection of traditional knowledge. However, they also acknowledged that it might be difficult to address these concerns

when access to such knowledge is sought for R&D. Companies were encouraged to support capacity building in indigenous communities and to enhance trust by accepting the customary law of these communities as the basis for negotiating for the disclosure of traditional knowledge. Companies were also urged to consider any benefit sharing that the communities might wish. On the other hand, it was accepted that companies would not pay benefits that exceed the economic value they assign to the knowledge disclosed.

It was underlined in the dialogue process that, in view of the legal uncertainties surrounding the protection of traditional knowledge, all parties must proceed with caution and in good faith; unrealistic expectations, high transaction costs, and the threat of public moral outrage could lead to a situation in which traditional knowledge becomes totally neglected as a resource for modern R&D.

The participants confirmed that companies must comply with the Convention on Biological Diversity and refrain from unauthorized appropriation of traditional knowledge through breach of confidentiality or through filing patents for knowledge that exists as prior art.

However, participants did acknowledge that traditional knowledge travels between cultures and that it may become incorporated in the public domain of modern societies. They proposed that scientific publication in ethnographic journals should not be sufficient to assume that the knowledge is accessible in the public domain.

The participants acknowledged that patents are one factor that affects access to essential medicines, alongside other factors such as poverty and the failure of state policies. It was also widely held that any solution must both account for the human right to health and sustain the incentives for future R&D.

The parties fully endorsed the Doha Declaration on the TRIPS Agreement, and Public Health of 2002, which affirms the right of states to use the safeguards provided in TRIPS (e.g., compulsory licensing) to cope with the health crisis in their respective countries. While, in general, company representatives held that other solutions, notably differential pricing, were more adequate, they accepted that they must respect the decisions of states and refrain from lobbying that attempts to undermine the use of the safeguards in TRIPS.

There was a broad consensus that companies should take steps to make essential drugs affordable to poor countries. It was pointed out, however, that such an obligation reflects the moral duty to help those in need; it cannot be framed in terms of the human right to health. This human right obliges the states, not private companies, directly.

It was widely understood that imposing a global order of intellectual property rights through TRIPS tends to favor developed more than developing countries, and that the acceptance of TRIPS will be seriously jeopardized if developed countries continue to fail to live up to their promises to grant market access for textiles and agricultural products from developing countries.

Introductory note by the Steering Committee

This report summarizes the results of a stakeholder dialogue process that dealt with some of the controversial issues of intellectual property rights (IPRs) in the application of modern biotechnology.

The process was launched by the World Business Council for Sustainable Development (WBCSD) in order to test a new format for getting companies to become responsive to criticism raised by stakeholders (non-governmental organizations and experts speaking on their behalf).

The process focused on IPR strategies related to pharmaceutical and medical R&D.¹ Its objective was to provide a forum for extended discussion and deliberation.

The underlying assumption was that the dialogue process could help to clarify the contested issues and possibly identify some common ground in the understanding of problems and perspectives, if not in the definition of solutions and strategies.

The process was explicitly designed to expose the business community to the views and concerns of its critics, and to explore what companies could do to take these views and concerns into account, given the economic framework in which they operate.

The dialogue process was organized and moderated by a team from the Social Science Research Center Berlin (WZB), Germany, and overseen by a Steering Committee elected by the participants.

The participants included representatives from major pharmaceutical companies and from non-governmental organizations, as well as renowned experts in IPRs and related fields (see list in the Appendix).

The dialogue progressed through a combination of face-to-face interaction at two conferences (in Montreux, May 2001, and in London, February 2002) and via extended electronic communications between the meetings.

The Science Center team supported the communication through the analysis and synthesis of arguments from the conference statements by the participants and relevant literature.²

The participants were divided into three working groups, each dealing with a topical area that draws considerable attention and conflict in the public debate:

- Access to human genetic resources
- Protection of traditional knowledge
- Access to essential medicines

Details on the issues and the cleavages that characterize these three areas are given in the respective introductory remarks to the conclusions of the dialogue process presented below.

The conclusions were overseen by the Steering Committee following a mandate from the participants. This mandate urged the Committee to assess the convergences and divergences of opinions in the dialogue process, indicate common ground, and report dissenting views.

We have tried to live up to this duty. Views that were not integrated into the statements are registered as footnotes. We apologize in advance for any errors that may have occurred. We ask the participants of the dialogue process to take a sympathetic attitude. It is understood that the statements listed in this report, while they result from the dialogue process, must not be read as firm commitments either by the individuals that participated or by the organizations that they represented.

These statements are meant to be a contribution to ongoing discussions and, more particularly, a signal which the WBCSD will send to its member companies.

¹ The stakeholder dialogue process was part of a comprehensive WBCSD project on "Innovation, Technology, Society and Sustainability", co-chaired by Jürgen Dormann (Aventis) and Chad Holliday (DuPont). Both this report and the report of the innovation project are available on the WBCSD's website (www.wbcd.org).

² Documents describing the framework of the dialogue process and the circulars in support of the electronic exchange can be downloaded from the WZB's website (www.wz-berlin.de/ipr-dialogue).



Access to human genetic resources

Human genetic research is becoming a key resource for the development of effective new medicines. Accordingly, pharmaceutical companies have a vital interest in knowing under what conditions such research, if pursued in a business context, would be regarded as legitimate and accepted by society. What rules should companies apply in collecting and storing data and samples from a large number of individuals? To what extent should pharmaceutical companies claim exclusive rights to use data and sample collections? What is the proper scope for intellectual property rights on research results, on the road to developing commercial products?

The participants of the stakeholder dialogue process addressed these questions in their deliberations. Main conclusions are summarized under three headings:

- protecting the autonomy, rights, and interests of research subjects
(informed consent, benefit sharing)
- balancing private and public uses of data and samples collected by companies
(research consortia, access to databases)
- calibrating intellectual property rights
(gene patents)



Protecting the autonomy, rights, and interests of research

Informed consent, benefit sharing

Background and contexts

The principle of informed consent is unchallenged. Views differ, however, with respect to the regulations this principle implies. Industry tends to take a formal rule-of-law view that emphasizes the autonomy of the research subjects. Accordingly, it should be the choice of the subjects to say “yes” or “no” to the conditions of the research relationship: for instance, whether or not to demand benefit sharing, allow data and samples to be stored after a research project ends, or give broad consent to future projects.

Stakeholders, in contrast, tend to take a substantive political view, emphasizing the contexts of power relations and inequality within which research subjects take decisions. From their perspective, informed consent is not just the acknowledgment of autonomy, but foremost a mechanism that empowers the weak to resist the strong. Accordingly, no decisions should be accepted by which research subjects give away control or do not use the options for control extensively.

In part, this difference may be more one of degree than of principle. After all, existing regulations do both: they acknowledge and strengthen subjective choice, and they impose some “objective” normative order that restrains choice. However, the difference is more profound. It makes it difficult to provide guidance for companies through a set of accepted rules that demarcate legitimate corporate behavior. Stakeholders tend to emphasize the need to take the

social contexts into account, within which such rules should operate. Thus compliance with accepted rules will be essential; but it will provide legitimacy only to the extent that the rules are perceived as constituting proper safeguards against the risks of genetic research and against the asymmetry of power and the hegemony of culture that prevails in society.

Building a trust relationship

Companies should take special care to demonstrate that the relationship they seek with the research subjects will be equal and fair and based on mutual respect. Companies need to demonstrate that the presumptions of mistrust are unwarranted, which are widely held in society because of the inequalities in terms of power and information between companies and research subjects.

The ethical order of the research relationship

Respect for autonomy is the most important principle for the protection of research subjects, but it is not the only yardstick of a legitimate research relationship. For example, the Helsinki Declaration determines that subjects cannot give consent to research that involves them in unreasonable risks. There are rules beyond informed consent that constitute the ethical order of the research relationship, and these must not be violated – even if the subject agrees. Companies should be particularly committed to these rules and possibly amend them with a view to giving additional legitimacy to research in the business context.

Protection against social risks of genetic research

The future uses of the results of human genetic research in society cannot be determined and monitored within the research relationship. However, the research will only be accepted if people can reasonably expect that misuse of the results and social risks from genetics will effectively be controlled.

Companies should support legal regulations that control such risks: data protection, anti-discrimination legislation, etc.

Value of genetic research

The dialogue process proceeded from the assumption that human genetic population research, if properly designed and controlled, may be valuable and in fact desirable, not only for companies, but also for society. While this premise was generally accepted, stakeholders pointed out that some communities could decide to opt out of such research as a matter of principle. It was acknowledged that communities have a right to do so, according to community rules, whenever the decision to participate in the research is a group-level decision. It was also accepted that (notwithstanding the requirement of individual consent) the basic decision of whether or not access to human genes should be granted for research belongs to society at large.³

Informed consent

Genuine consent: the right to say “no”

All parties in the dialogue process agreed that genuine consent by the

arch subjects is a precondition for including their data and samples in the research. The modalities of “consent” must be determined from the cultural perspectives of the subjects, i.e., on the basis of their perceptions and values, not from the professional framework of the researchers. Subjects must be completely free to say “no” to the research, and no attempt should be made to coerce, manipulate or “buy” them into participation.

Explicit consent: the need to opt in

Public interest may justify exemptions from the requirements of informed consent. National legal regulation and professional tradition allow researchers, in certain cases, to draw on personal (identifiable) data and samples of subjects without consent or with reference to presumed consent. Companies should not use any of these exemptions for research in the business context. Rather, they should commit themselves unequivocally to the principle of explicit consent. They should always ask participants to opt into the research and not be content with the provision that participants can opt out – even if national law permits such an approach.⁴

Informed consent and the use of databases

Companies should not use databases that collect personal data and samples without explicit informed consent. Exemptions from informed consent, which may be justifiable in the public interest, should not be exploited for private research.

Withdrawal of data and samples

The Helsinki Declaration rules that subjects in medical research can withdraw their participation at any time. The right to withdraw is an

element of the ethical order of research with human subjects, and it cannot be renounced in informed consent. Companies emphasize that the rule fully applies when subjects contribute their personal data and biological samples. Subjects should, however, be free to authorize the anonymization of the data or the use of samples that make withdrawal unfeasible in practical terms, such as their incorporation into secondary products.

Sharing samples and data

Anonymous data and samples incorporated in further products cannot be withdrawn. Data or samples shared (with consent) with research partners can, however, be withdrawn as long as they are identifiable.

Informed consent for commercial uses

Companies shall disclose the commercial uses they envisage for the data and samples collected, and get informed consent for such use. Disclosure shall include the intention to develop secondary products (e.g., cell lines) from samples and to claim IPRs (patents) for inventions derived from the research based on the collected data and samples.

Unforeseen purposes of research: re-consent

If data and samples are to be used for other purposes than those agreed upon in the informed consent process, companies should always go back to the subjects and ask for new consent, unless data and samples were anonymized with the initial consent.⁵ But it is acknowledged that the administrative burden of obtaining re-consent could be minimized by allowing consent for circumscribed areas of disease.

Collected data: storage and use

Collections of (non-anonymized) data and samples constitute valuable resources for future research. Therefore companies should, with due consent, be allowed to store them over a longer period.⁶ However, the use of the stored data and samples may be blocked under the requirement of re-consent, if people are out of reach or if they are deceased.⁷

Anonymous data and samples

Data and samples anonymized with consent may be stored and used without restrictions, within the rules of law and the provisions of the competent ethical review committee.

Broad consent: purposes of research

If the research projects for which data and samples are supposed to be used cannot be fully specified at the time when consent would be requested, the subjects cannot, strictly speaking, become fully informed. Participants concluded that subjects could nevertheless give consent in such cases, if they feel that they have sufficient trust. The crucial point is that consent must be genuine and emanate from the value system and assessment of the subjects, not of the researchers. Subjects may, for instance, decide whether or not to agree with the use of their data and samples in future research for circumscribed areas of disease. Such consent avoids blanket authorization for unlimited purposes, on the one hand, but makes the administrative burden of obtaining re-consent redundant, on the other. All future research projects have to be evaluated by appropriate ethical review bodies.

Research in developing countries

Companies from the North should be particularly careful in research projects

not to take advantage of poor, uninformed local people from the South; they should not, however, as a matter of principle, refrain from doing research in the South. As one stakeholder from the South put it, exclusion is now at the center of inequity, not exploitation. It is therefore important to establish decent and transparent research relationships with local communities.

Community consent

Whether individual informed consent is sufficient to legitimize the collection of personal data and samples depends on the culture of the community. Traditional or indigenous communities tend to require approval by the group. Modern communities tend to leave the decision with the individual, within the confines of legal regulations. When community consent is required, its refusal overrides the consent of the individual to participate; but community approval is not a substitute for the lack of individual consent.

Groups affected by the research

It was discussed whether groups who could possibly be affected by the outcome of the research should have the right to authorize and, if they deem it necessary, to veto the research. In this case the need to negotiate informed consent would be extended to a large number of groups (patients, gene carriers, age groups, ethnic groups, persons seeking insurance or employment, etc.) who do not form a proper community and have no mandate to speak for, and act on behalf of, the research subject. The participants of the dialogue process felt that the legitimate concerns of such groups should be addressed by legal regulation, but not by including them in the consent requirement.

Community consultation

It was considered appropriate, however, that companies consult with groups in society that may possibly be affected by the consequences of the research and, eventually, support demands for regulations that protect these groups.⁸

Ethical review

Industry acknowledges that all research that draws on the collected data and samples should be reviewed by an ethics committee to ensure that the relationship with the subjects of research is balanced – i.e., that the research design complies with the stipulations of the informed consent and with general rules that may apply. It is understood that such committees should be independent and include genuine third parties not associated with the company. Approval by an appropriate ethics committee may be taken as a kind of community consent.⁹

Social risks of genetic research

Social risks of genetic research and the question whether genetic research should be allowed must be dealt with through societal regulation. Beyond such regulation, individuals (and communities) can refuse informed consent if the research, according to their own assessment, implies unacceptable social risks. It remained unresolved in the dialogue process whether or not social risks must be disclosed in the informed consent process, and whose standards researchers must apply in order to decide what they have to disclose.

Benefit sharing

Questions regarding benefit sharing with human subjects involved in genetic research can trigger responses in which, paradoxically, the parties

change sides. Companies may appeal to altruism, and they may frame participation in research as cooperation for the production of a public good (even if that good would eventually be achieved through commercial development); stakeholders, in contrast, may emphasize the economic self-interest of donors, and they may find acceptable the commodification of data and samples, as well as a business perspective on research participation. In the dialogue process there was some convergence (legal restraints such as those imposed by the Convention on Biological Diversity notwithstanding) on the idea that research subjects should be able to decide whether they want benefit sharing or not.

Benefit sharing: control of data and samples

Negotiations over benefit sharing must start from the principle that research subjects have control over their data and samples. Accordingly, the subjects must decide whether, and under what conditions, the data and samples can be used.

Benefit sharing: diversity in culture matters

It was a common understanding in the dialogue process that whether or not individuals or communities participating in research should demand benefit sharing is an issue that must be decided upon according to the cultural values and orientations of the individual or community.¹⁰

No one-size-fits-all model

Except for regulations that make benefit sharing obligatory (such as the Convention on Biological Diversity in the case of non-human genetic resources), the question of benefit sharing is largely a matter of negotiations during the informed

consent process. Companies may appeal to altruism and ask for participation in research as a gift, even though the goal is a commercial product. On the other side, subjects may regard such participation as a business relationship and pursue their own financial interests.

Prevent the “buying” of subjects

Most participants, representatives from industry and stakeholders alike, warned that turning research participation into a commodity undermines informed consent and leads to “buying” the consent of subjects. Especially under conditions of poverty, the offering of monetary incentives or other material benefits might amount to coercion.

Benefit sharing to ensure freedom to operate

Since companies want to ensure freedom to operate they are reluctant to enter benefit sharing arrangements that grant financial reach through claims on future rights and profits derived from the research. In addition, it is virtually impossible to quantify the extent to which such rights and profits might be attributed to the contribution of single research subjects. There are, however, also cases in which companies want to offer financial rewards in exchange for specific contributions from subjects regarding

their rights over data or samples. Either sort of arrangement should be considered as possible and negotiable, provided that there is genuine consent and that the deal is not ethically objectionable – a matter, which, in any case, would have to be attested to by an ethical review committee.

Indirect benefits

It was admitted that new drugs, scientific progress, and economic growth flowing from the research provide individuals (and communities) who participate in the research with some indirect benefits. It was also pointed out, however, that such benefits are less likely to accrue if the community from which the data and samples are retrieved is not the community in which the commercial development and production takes place. Thus special issues of equity and benefit sharing arise when Northern companies pursue research with subject populations from the South or from indigenous communities.

Non-monetary benefits

Companies and research subjects can (and sometimes do) negotiate benefit sharing in terms of preferential access to products (diagnostic or therapeutics) that will be derived from the research. In North-South relationships, especially with indigenous communities, such benefit sharing schemes are advised as

good practice, because the subjects and their communities would normally not be included in the flow of indirect (scientific and economic) benefits from the research activities in which they participate.¹¹

Gift relationship & pricing policies

The gift culture of providing data and samples for research is based on the understanding of the subjects (echoed by the companies) that they will contribute to the public good of medical progress, even though the research is aimed at developing commercial products. This understanding will quickly erode if the products prove to be unaffordable for the subjects or their families or patient groups to which they belong.

Negotiating pricing & licensing policies

Participants in the dialogue process discussed some recent cases in which unreasonable prices were sought for genetic tests developed from research with human subjects. They proposed that subjects negotiate, and companies offer, arrangements that exclude such pricing policies. While, in general, it may seem difficult for companies to have their pricing policies discussed in negotiations with research subjects, such arrangements may only commit the companies to those policies which they advertise publicly anyway.

³ It was pointed out as a problem that ethical objections which are culture-specific could block access to human genes that might be beneficial for human health in general. The solution seems to be that in such a case the requisite research is shifted to countries that do not object to access to human genes for moral reasons.

⁴ One participant from industry expressed the desire to have uniform informed consent requirements, i.e., irrespective of whether research would be undertaken by public or private organizations. Another participant from industry endorsed the above statement for the future but considered it inappropriate if industry uses data (or samples) it has legally obtained under a presumed consent rule in the past. In those cases industry should not be obliged to seek explicit consent from the subjects retroactively.

⁵ The proposal made by a participant from industry, to confine the need for re-consent to a period of, say, ten years, was not widely accepted.

⁶ One stakeholder requested, instead, that all data and samples should, as a rule, be destroyed once the agreed upon research has been accomplished.

⁷ One participant suggested that in this case the data and samples might still be used if they were removed from the exclusive realm of the company and placed under the rules and controls of public research.

⁸ One participant from industry argued that community consultation should not be a general policy with every single research project. Rather, the ethical review body should advise the company when to seek community consultation.

⁹ One participant pointed out that ethics committees, if they cannot rely on existing regulations, might apply ethical standards that are highly controversial in modern societies. In such cases, companies may consider the review as not binding. They should, however, expose themselves to the discussion invoked by such reviews.

¹⁰ One stakeholder held, however, that research participation without benefit sharing is unethical.

¹¹ Some stakeholders argued that such BS should be extended to all subjects and communities involved in the research of the company not just to those who happen to provide data and samples that lead to successful developments.

Balancing private and public uses of data and samples collected by companies: research consortia and access to databases

Research consortia (RC)

The working group discussed research consortia that are explicitly designed to release their results to the public domain. The prime example in the discussion was the SNP consortium. While participants agreed that such research consortia might be feasible and useful, they differed in the interpretation of their significance and preconditions.

Stakeholders tend to welcome these consortia because they enlarge the public domain and restore a balance between private and public knowledge, which, in their view, is increasingly being upset by a race among industry and universities for patents on basic genetic information and research tools, far ahead of product-related inventions.

Industry, in contrast, views such research consortia as a pragmatic approach to distribute and reduce the costs and risks of research in areas that they consider pre-competitive. They may also be in favor of shifting some knowledge to the public domain, because that preempts the patenting of the knowledge by competitors.

However, industry sees no general need to rebalance the private-public relationship. They trust that excessive patent applications will be turned down by the patent offices anyway, and that, despite patent protection, research tools will be available on reasonable licensing terms.

Companies should explore their flexibilities

Dialogue participants agreed that research consortia that release their results to the public domain or make them otherwise generally available might be a viable strategy to advance the knowledge in complex fields of genetics. Therefore, they encourage companies to explore the flexibilities they may have to engage in such research consortia.

Viability of research consortia

Research consortia that release results to the public domain are a viable option, only if such release is compatible with the proprietary interests and conditions of companies, especially with the need to justify and protect the investment in the research.

Different company schemes

Admittedly, different companies may have different flexibilities. Small start-ups that use patents on research tools to raise money on the venture capital market will have fewer options to join research consortia that release results to the public domain than will large companies that develop end-products for consumers.

Research consortia address public concerns

Whether the patent system functions well in the field of genetic research and development is a controversial issue. There are serious public concerns that basic knowledge at the frontiers of genetic science will be

protected by patents and subsequently appropriated for exclusive private use. Research consortia that release results to the public domain are a perfect means to address these concerns. Such consortia will undoubtedly contribute to the legitimacy of claiming exclusive rights to inventions further down the line toward products.

Public-private partnerships in research consortia

Experience shows that companies also engage in research consortia in the fields of structural and functional genomics, or proteomics, provided the research is still at a distance from product development. Governments (and charities) are encouraged to support joint public-private research consortia, in order to increase the options to retain basic knowledge from these fields in the public domain. Yet, companies need to assess the advantages of public support. Indeed, resorting to public funding might imply that they would not be entitled to claim exclusive rights to use the knowledge generated within the research consortia.

Access to databases

A leading question in the discussions of the working group was whether special rules should apply for databases built by private companies with public support. The case of the Icelandic Health Sector Database provided the starting point for these discussions.

Participants acknowledged that the rules for access to such databases must recognize investments made in order to have the databases in the first place. On the other hand, they also acknowledged that access to databases built with public support should be non-exclusive and cheap.

Databases as public infrastructure

Databases (including sample collections) built with public support should be accessible as public infrastructure, irrespective of whether the database operates under schemes of public or private law. Public support could either mean public spending or authorizing the inclusion of data collected in the public sector, or granting an exclusive license to build up the database.

The principle of non-exclusive access

Access to such databases should be granted, with due respect for privacy protection, on a non-discriminatory basis to anyone who has the competence to use it. Exclusive licenses to use the databases should not be issued; they are hardly compatible with the function of the databases as public infrastructure.

The case of clinical trial data

The principle of non-exclusive access to databases built with public support was adopted by the participants for databases to be used as research tools.¹² Databases for product proof (clinical trial data) may warrant a different rule.

Fees for access

Fees for access can be appropriate to recover some of the costs for building and operating a database. Such fees will, however, exclude users if they are too high. The first priority must be to ensure that the database will be used as widely as possible to get maximum societal return from the investment in public infrastructure. Special allowances should be made for poor users from developing countries.

Higher fees for companies

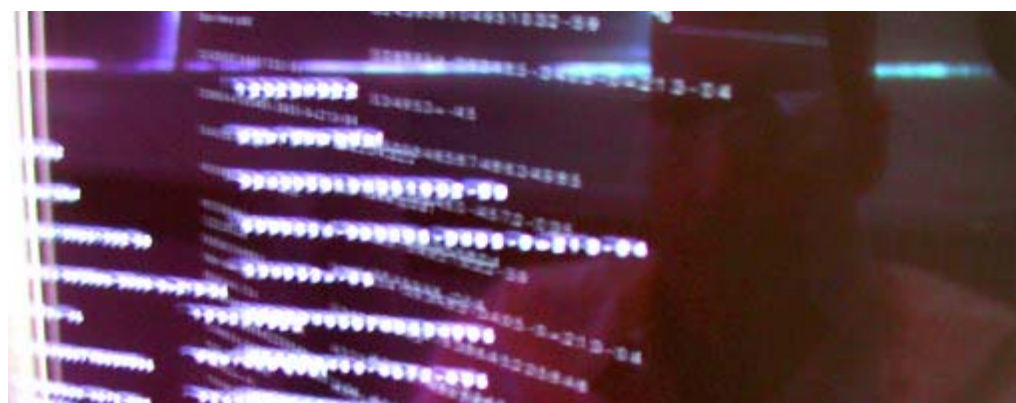
In many cases, companies charge higher fees for access to databases than do academic researchers. The participants regard this practice as acceptable. However, care must be taken, that the use and the usefulness of a database is not obstructed by the pricing scheme.

Databases within companies

The participants encourage companies to ensure that their databases are accessible for wide use in society, wherever this is compatible with companies' proprietary imperatives. Companies could also consider the transfer of old collections, which otherwise would be lost or would never go into general use, under public control.

No reach-through provisions

Participants concluded that, as a rule, holders of databases should not require (and the user should not accept) that, in exchange for access, reach-throughs be granted on results or rights the user may obtain from the results achieved by using the databases.



¹²A question discussed (but left open by the participants) is whether databases that comprise results (publications) from publicly funded research should not also be accessible as public infrastructure.



Calibrating intellectual property rights

Patents on genes

Patents on genes are contested. The participants of the dialogue process could not resolve the controversial issues. While in some cases they had a common understanding of the issues raised by patents on genes, their approaches to these issues were vastly different.

Representatives of industry tended to start from the existing frameworks of patent law and considered how these frameworks may be applied and/or (if necessary) amended to cope with problems.

Stakeholders, in contrast, wanted to take a broader perspective. They urged that alternatives to the patent system be discussed, and they challenged the notion that patents on genes are needed to reward invention and protect investment in life sciences.

No consensual conclusions were reached; however, at various points, the parties found some common ground.

Representatives of industry considered the possibility to modify patenting strategies to address some of the stakeholder concerns.

Stakeholders, notwithstanding their rejection of gene patents in principle, acknowledged that there might be modifications which, in their view, are steps in the right direction.

The following sections try to capture both the divergence of opinions and the common ground found in the

discussions. For the sake of clarity it should be noted that the representation of industry in the dialogue process was biased toward large pharmaceutical corporations.

Alternatives to the patent system

The debate over whether patents should be granted is as old as the patent system itself. The discussion in the dialogue process on alternatives to patents echoed that debate. While representatives from industry emphasized that the patent system has emerged as the best solution to balance societal interests in the promotion and dissemination of useful information, stakeholders insisted that alternatives to the patent system are possible and necessary. No consensus was reached in this respect. However, the participants did converge in the opinion that patents do serve functions that would also have to be met, if alternative systems were in place: namely, to reward invention and provide incentives to invest in R&D.

Criticisms of the patent system

Stakeholders saw the public debate over patents on genes as indicative of a deeper crisis in the patent system. They see patents as pursuing a winner-takes-all model, which is at odds with the incremental and collaborative character of modern R&D processes. In the opinion of stakeholders, patents serve more to protect investment than to reward invention; and stakeholders hold

further that patents restrict the freedom of research and block innovation. Therefore, stakeholders call for alternatives to the patent system to be devised and implemented.

Adaptive capacity of the patent system

Representatives of industry argued that the patent system has worked well in the past and that it is the most appropriate legal system to balance investment risks, rewards for creativity, and early disclosure, in order to advance progress toward inventions benefiting the public.¹³ Without the patent system, private investment in R&D, for example, for new drugs, could not be mobilized. Questions that might arise in the context of patents on genes could be addressed through adaptation within the patent system.

The need to protect investment

Stakeholders acknowledged that companies have to make a profit, but that, if alternatives to the patent system were sought, then alternative models of financing R&D would be required.¹⁴

The moral aspects of patents on genes

Among the objections raised specifically against patents on genes, moral arguments are the most basic.

There are strong voices in the public debate claiming that patents on genes should not be granted as a matter of principle, because gene

patents violate the moral order. However, there is no consensus among societies with respect to the moral standards that ought to apply.

In the dialogue process, representatives of industry referred to existing patent laws and court rulings. They pointed out that claims for (human) genes are not comparable to claims for human reproductive cloning or producing human-animal chimeras – examples of inventions, the exploitation of which is considered immoral under the European Directive (Art. 6-2). Further, representatives of industry held that patents on genes could not offend human dignity, because gene patents do not confer any ownership on individual human beings.

In contrast, some stakeholders applied a broader moral framework. For them, granting exclusive rights to components or structures of life would constitute a serious devaluation of life and an improper way for humans to relate to nature. Therefore, they consider patents on genes to be fundamentally wrong.

Dialogue participants disagreed over these issues, but they agreed on some features and implications of their disagreement.

Acknowledgement of moral diversity

Participants disagreed as to whether patents on genes contradict moral rules. They acknowledged, however, that this disagreement reflects the diversity of moral views in the society. People draw the lines differently: for some it is obvious that patents on genes constitute a breach of morality; for others this is clearly not the case.

Moral coercion through majority rule

Participants also acknowledged that legal rules allowing genes to be patented offend the beliefs of those who object to such patents for moral reasons, and, further, that these individuals may find it coercive to have to live in a society that grants such patents. However, such coercion is common in modern societies; it follows from the principles of democratic majority government. For example, in many countries, people who object to abortion for fundamental moral reasons must nevertheless live with the fact that the practice of abortion is spreading.

Public rules and personal moral views

People should not be obliged to violate their own moral beliefs. However, this principle does not yield a right to dismiss public rules, even if such rules are seen to be in conflict with personal moral views. Normally, individuals can only choose, within their own private sphere, to dissociate themselves from practices that they consider immoral. Thus, they may decide, for instance, not to use products based on gene patents. However, they cannot ignore the legality of such patents. A different conclusion would only be warranted if basic human rights or key elements of the rule of law were at stake.

Evolving moral frameworks

While some stakeholders insisted that, for them, patents on genes raise fundamental moral issues of how humans should properly place themselves in nature and how they should deal with life, it was generally acknowledged that such moral tenets do not have the status of basic

human rights. It was, however, also accepted that moral frameworks are dynamic in modern cultures.

Discussions over patents on genes will continue. Should a predominant view evolve that such patents indeed violate morality, then the laws allowing such patents will certainly have to be reconsidered.

Policy aspects of calibrating patents on genes

Many of the arguments challenging patents on genes are not on the level of fundamental moral concerns: rather, they are policy considerations of how invention can be properly rewarded and innovation promoted, how a balance can be struck between exclusive rights and open access.

Stakeholders in the dialogue process, while underlining their rejection of patents on genes in principle, involved themselves in discussions over the more pragmatic questions of whether companies do in fact need patents on genes to protect their proprietary interests, and how the scope of such patents should be calibrated – and possibly restricted.

In view of the fact that patent legislation is still pending in many countries, and that few court rulings have been issued to clarify the scope of protection granted by gene patents, the discussions focused mainly on rules (and interpretation of rules) that the companies could live with. While one representative of industry pointed out that companies (like everybody else) occasionally defend what they have and consider the maximum protection they can

get as a functional necessity, others emphasized that this is not the general attitude. Representatives of industry agreed with the need to acknowledge differences of opinion, have a dialogue, and find compromise.

The discussions in the dialogue process revealed some flexibility, as reflected in the following statements.

Controversial: the need for patents on genes

There was no consensus over whether patents on genes are necessary to provide the R&D investments needed for the invention of new medicines.

Representatives of industry disagreed with the position that patents on end-products are sufficient; patents on intermediary results (research tools), such as drug targets, may well be essential. Also, in their view, other mechanisms that protect investment in research, such as exclusive rights on clinical trial data or orphan drug regulations, cannot always substitute for patent protection on research tools.

Scope of patents on genes

All participants acknowledged that patents should only be granted for inventions, not for discoveries.

There was consensus that this rule excludes patents on genes per se in their naturally occurring state. However, representatives of industry did not accept that genes isolated from their natural state and purified should also not be patentable as a rule. Instead they held that the European Directive struck an appropriate compromise ruling that mere DNA sequence information

without indication of a function is not patentable, but that patents can be filed if the gene function and a utility/industrial application (for example, as a drug target) is specified.

Legal perspectives

Participants from industry pointed out that one can only determine with certainty the scope of patents on genes after the appeal courts have clarified the meaning of the statutory requirements.

Representatives of industry envisaged the possibility that European law might require that the gene function be indicated in the patent claims, and that this requirement could potentially limit patent protection to the function disclosed. Some representatives from industry conceded that they could live with such a rule.¹⁵

Patents on genes must not restrict freedom of research

All participants proceeded from the premise that patents on genes must not be used to bar access to building blocks of science or to research tools. Industry, however, argued that, in fact, no problems exist in this respect, because research tools are often available at a reasonable price, or that research exemptions exist in many countries allowing the use of patented knowledge under specific conditions.

In addition they emphasized that it is the policy in many companies to license research rights generously and not to litigate against researchers in academic institutions.¹⁶

However, problems may arise nevertheless, since research

exemptions only allow for experimenting on an invention, i.e., testing, but not with an invention, i.e., the use of the subject matter for the purpose for which it had been developed. Accordingly, such a "use" would necessarily conflict with the exclusive rights of title-holders. In this regard, the group acknowledged the need for the development of a "fair experimental use" doctrine which addresses especially the issue of research tools.

Safeguards to protect freedom of research

An underlying expectation in this discussion was that companies should pledge to make the goodwill policy of granting access for research purposes a stable and sustainable pattern. It was understood that strong research exemptions are needed to underpin such commitment, and that options for compulsory licenses to guarantee freedom to do research should be available if companies are uncooperative.

The balance with the legitimate concerns of inventors

On the other hand, the principle of freedom of research cannot authorize unlimited use of inventions. There is still the need to balance the interest to facilitate access to research tools with the need to provide a fair amount of control/exclusivity to the inventor, because of the effort, time, and investment risk undertaken by the inventor. In general, patentees will find it easier to provide access to proprietary technology, if the use is truly restricted to research or at least to a use within a developing country where there would be no export of products.

Coping with the patent thicket: licensing

Representatives of industry argued that there is no reason, nor any convincing evidence to assume that patents on genes will block innovation. While broad patent protection may mean that one has to get a license for any dependent innovation that uses the gene (even if the innovation is unrelated to the utility disclosed in the original gene patent), licensing and cross-licensing are said to be normal and adequate instruments to cope with the patent thicket.

They also pointed out that patents on genes are unlikely to block the commercialization of downstream innovation, because there is a trend among patent-granting authorities to narrow down claims so as to prevent undue restrictions of follow-up inventions.

Unwanted corporate strategies

Industry acknowledged, however, that there are cases in which companies charge prices for patented technology, for example, for genetic tests, which may in fact mean that the technology cannot be widely used.

They also acknowledged that dependent patent holders could not expect that cooperation on reasonable terms could be achieved in every case. Some companies demand royalties that are clearly unacceptable.¹⁷

Empirical questions

Participants agreed that it was desirable to collect more empirical data on the practices of licensing and cooperation that evolve around gene patents, in order to determine

whether or not problems of access to research tools and blocking innovations exist.

The option for a compulsory license

Participants agreed that legal safeguards are needed to protect the freedom of innovation. Holders of dependent patents should be able to seek a compulsory license for improvements if they cannot reach a deal with the holders of gene patents.¹⁸

Special protection of the interests of developing countries

The effects of patents on genes on developing countries were a key concern of stakeholders in the dialogue process.

Stakeholders argued that gene patents exclude developing countries from access to new technology.

Representatives of industry pointed out that few gene-related patents are filed in developing countries, and even fewer granted. In their view, access to new technology is inhibited through lack of resources and infrastructure, rather than through exclusive intellectual property rights. The companies emphasized that they have no interest in blocking research in developing countries, and that they are willing to collaborate through licensing or joint ventures. While patent protection by definition imposes restrictions on the access to protected technology, it remained an open question in the discussion whether, or to what extent, developing countries are particularly at a disadvantage through such protection.

Some representatives from industry pointed out that it is to the advantage of developing countries to implement appropriate IPRs in order to promote a fair equilibrium between industry and developing countries and to guarantee the recognition of developing countries' innovations. India's (starting) pharmaceutical industry, which is clearly pro-patenting, provides a good example.

Some stakeholders took the perspective of indigenous communities and argued that the extension of patent protection driven by the WTO/TRIPS framework constitutes injustice per se. They held that the extension of patent protection replaces traditional systems of intellectual property, for example, collective ownership of knowledge schemes implied in customary law, and that it deprives indigenous communities of the right to operate under their own cultural, social, and legal values.

There were few lines of convergence in this discussion, but it was acknowledged that special safeguards should be explored which respond to the concerns voiced by representatives of developing countries.

Empirical questions

There was an implied understanding that more empirical investigation is needed to determine whether, or in what respect, developing countries are disadvantaged through the granting of patents on genes. In particular, one needs to find out whether (and why) mechanisms that mitigate the exclusive effects of patent protection in the North may not work well in the South.¹⁹

Support for challenging patents

Experience proves that many patent claims fail if they are challenged in courts. However, high litigation costs and scarcity of legal expertise are hurdles for developing countries, hindering their ability to legally challenge patents they consider invalid.

Many participants, also from industry, acknowledged that some mechanisms should be introduced to help developing countries challenge patents. An initial step might be compulsory public disclosure when a patent has been successfully challenged in any country, or a rule that allows abridged procedures in a developing country in the case of final invalidation of a patent in a Northern country. It is understood that such a rule would respect the defense rights of patent holders in appeal procedures.

Discussion of new ideas

Representatives of industry agreed that it might be worthwhile to discuss new ideas for special consideration of developing countries' needs. The model of the FAO International Seed

Treaty was cited in this respect. The treaty guarantees free access to important agricultural genetic resources included in a multilateral system, and limits the possibility to get patent rights on these resources. It could be explored whether a similar model might be developed for other genetic resources as well, on a case-by-case basis and through international agreements.

¹³ One participant (industry) argued that there is no statistical evidence that the patent system has a negative impact on scientific dynamics of research and on the rate of innovation in industrialized countries. One possible comment to this argument is that aggregate data will not account for and accordingly miss single cases which may nevertheless be significant. Thus, there seems to be a need for detailed empirical studies, see also statement under Empirical questions on page 15.

¹⁴ One idea that came up in the discussion was that the whole R&D chain for new drugs be transferred to (and financed by) the public sector, while private companies be confined to the production of the drugs. The proposal was not discussed at length, but there was a common understanding that alternatives to the patent system would imply major revisions of existing legal, institutional, and allocation arrangements.

¹⁵ One participant from industry proposed that the following statement be made:
"Representatives of industry envisaged that European law will require that the gene function be indicated in the patent claims, and that this requirement will limit patent protection to the function disclosed. They indicated that this interpretation is seen as appropriate."

¹⁶ One participant from industry proposed that the last three sentences be replaced with:
"Representatives of industry, however, argued that, as one of its seminal and intentional aspects, patenting forces the dissemination of knowledge that otherwise may not be disclosed, and that no patent restricts research. Thus, patents foster additional innovation and research rather than inhibiting it."

¹⁷ One participant from industry disagreed with the statement and proposed the following amendment: While it could be acknowledged that access to patented technologies "(as in all other walks of life) is limited by their affordability[.], providing such access and affordability is, however, a societal issue that, for the most part, is subject to the same free market framework as all other commercial activity."

¹⁸ One participant from industry withheld agreement with the last sentence.

¹⁹ One participant from industry pointed out that it should also be investigated whether and to what extent cheap and rapid access of developing countries to the patent system would counterbalance any disadvantage.



Protection of traditional knowledge

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”.²⁰

The protection of traditional knowledge was included as a topic in the dialogue process on intellectual property rights because 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 traditional knowledge.

Concerns and perspectives

Beyond this basic assumption, however, participants differed profoundly in the concerns and perspectives they associate with the protection of traditional knowledge.

Companies tended to take a narrow perspective and focus on questions of how traditional knowledge can be used legitimately for R&D in a business framework. They acknowledged that they must respect the rights of the holders of traditional knowledge 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 traditional knowledge, 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 traditional knowledge, 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

traditional knowledge in R&D, regardless of whether or not legal rules and contractual obligations have been complied with.

Indigenous people (and NGOs and experts speaking on their behalf) took a much broader perspective. For them protection of traditional knowledge cannot be reduced to questions of access to knowledge and of intellectual property. Instead, they consider it as integrated with their ongoing struggles to defend the integrity of their cultures and regain the autonomy of their communities.

Protection of traditional knowledge 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 traditional knowledge are addressed by indigenous people. 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 cultural integrity and take the needs of indigenous communities into account. For instance, the nature of traditional knowledge could mean that the knowledge is only allowed to be transferred orally and not in written form. And that not just one person but a group of indigenous people retains this knowledge. This differentiates it from the requirements/nature of the current patent system.

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 traditional knowledge at great length; but, in principle, the companies acknowledged the concerns raised by the indigenous people. 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 traditional knowledge 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 people 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 traditional knowledge. A more difficult question was what rules should apply if the traditional knowledge 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 (CEPIC),²¹ which may be appropriate to accommodate conflicting interests better.

The participants did not try to demarcate which traditional knowledge 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 traditional knowledge 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, traditional knowledge.

The participants of the working group agreed that the broader issues associated with the protection of traditional knowledge should be acknowledged explicitly in a final section of the paper.



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."

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

²² The WIPO also relegates the definition of what constitutes traditional knowledge 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 www.wipo.int/globalissues/index-en.html

A Preamble

The group urges the acknowledgement of the cultural, spiritual, and economic value of traditional knowledge, innovations and practices, especially to the communities themselves.

The group also agrees that protecting and maintaining traditional knowledge is an urgent priority and that all stakeholders must respect the cultural integrity of the holders of traditional knowledge and the laws on which their communities are based,²³ in keeping with established international human rights standards.²⁴

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 worldwide 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.

This imbalance is inherently unfair and needs to be addressed.²⁶ In this respect, the group acknowledges work undertaken by WIPO to better protect traditional knowledge and the interests of its holders and to explore traditional knowledge holders' own informal IPR-like regimes based on customary law.²⁷

There have been many recent cases of commercial use of biodiversity involving

traditional knowledge that need to be studied for useful lessons.

Traditional communities and individual experts among them who generate, reproduce, sustain, and refine traditional knowledge have a right to a fair and equitable share of benefits arising from the commercial use of their knowledge.

Traditional communities and traditional knowledge²⁸ holders have the right to say "no" to commercial use of their knowledge.

Companies must acquire the prior informed consent (PIC) of traditional knowledge holders before they seek IPR protection of innovations arising from their research.

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 traditional knowledge, 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."

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.

Objectives and common ground

Basic objectives of indigenous communities²⁹

Indigenous people consider the protection of traditional knowledge as an element of their broader struggle for self-determination, land rights and political autonomy.

Indigenous people see an urgent need to protect, promote and conserve traditional knowledge, because it is a binding and preserving factor for indigenous communities. However, because of lack of recognition and compensation, traditional knowledge is losing significance for the communities and is disappearing at an accelerating rate.

Indigenous people are concerned that the value generated through traditional knowledge is not adequately recognized and compensated. It should be acknowledged that the protection, promotion and conservation of traditional knowledge are important for global environmental security and food supply.

Indigenous people seek protection to prevent unauthorized appropriation of traditional knowledge and to ensure a fair and equitable sharing of benefits arising from the use of that knowledge. It must be prevented that traditional knowledge is appropriated, adapted, and patented with no compensation to its custodians and without their prior informed consent.

Indigenous people 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.

For indigenous people, protection of traditional knowledge and changes in the IPR system are necessary to bring equity to the essentially unjust and unequal relations between the traditional and modern parts of the world.

Basic objectives of companies

Companies want access to traditional knowledge 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.

Companies therefore strongly advocate that rules be set up that are generally accepted and clearly tell when and how traditional knowledge can be used legitimately by private companies. Most important in this respect are rules to demarcate the protected traditional knowledge and identify its legitimate holders.

Companies must be able to evaluate whether envisaged activities are likely to infringe upon protected traditional knowledge. And they must be able to know whom they should address to negotiate consent and benefit sharing.

Such rules should be voluntary to allow flexibility and learning. If the rules bring about successful cooperation in the use of traditional knowledge, they will become paradigmatic and, as a matter of fact, binding.

Common ground: routes to be taken

Accepted rules/regulations that resolve the issues of legitimate access to traditional knowledge at the international level are still under development. Existing rules/regulations are limited to national territories.³⁰

Participants share the understanding that all those involved in access to traditional knowledge necessarily operate under conditions of normative or moral uncertainty. General legal frameworks that may apply (such as the ABS Guidelines of the Convention on Biological Diversity) do not provide specific guidance.

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, 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 traditional knowledge to make some of their traditional practices and

achievements accessible for commercial, profit-making purposes.

When seeking access to traditional knowledge, companies commit themselves to recognizing the customary laws of the societies of knowledge holders, and to basing their approaches on those established customs when negotiating consent and benefit sharing.

Companies and holders of traditional knowledge 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.

Companies acknowledge that trust building is essential in dealing with traditional (indigenous) communities.

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 traditional knowledge. 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. Companies/third parties cannot obtain patents, copyrights, or other legal IPR protection for the traditional

knowledge of indigenous people 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 people whenever they offer for public display or sale products based on traditional knowledge.

In the current situation, where the standards for the protection of traditional knowledge 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.

Common ground: mistakes to be avoided

Companies should refrain from any attempt to get access to traditional knowledge by acts that imply breach of confidentiality, espionage, or other invasions of the privacy of indigenous communities.

Companies should not file patents or apply any other instrument to claim rights over traditional knowledge

without the consent of the holders. Such claims would violate the respect and acknowledgement owed to the holders of traditional knowledge. In most countries such patents should not be granted anyway because existing traditional knowledge 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.

Holders of traditional knowledge 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.

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

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 people and did not meet with any objections. The Steering Committee considered the statements made in this paragraph to be a fair representation of main objectives.

³⁰ In this respect, one participant recommended that results be taken into account, which were attained elsewhere. See, for instance, the "Suggested Ethical Guidelines for Accessing and Exploring Biodiversity – The Pew Conservation Scholars Initiative" in Eubios, *Journal of Asian and International Bioethics*, 5 (2), (March 1995), pp. 38-40, see www.biol.tsukuba.ac.jp/~macer/EJAIB52.htm

³¹ One participant (NGO) 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."

Exploring the options and obligations for companies

What companies should do within contractual relationships with holders of traditional knowledge?

Companies should declare that they acknowledge the local rules indigenous communities have with respect to the use of traditional knowledge. They should commit themselves to abide by those rules and to follow the underlying principles, also in the run-up to any such negotiations.

Companies should accept the definition of indigenous communities as to who the rightful holders of traditional knowledge 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.

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 traditional knowledge. If partners fail to establish their right to traditional knowledge, companies can retreat from the contract and, instead, enter into negotiations with the legitimate holder of that knowledge.

Disputes over what constitutes traditional knowledge may be

endless and divisive. Companies should accept as traditional knowledge what their partners disclose as traditional knowledge. They can decide not to close a deal if they think the claims of their indigenous partners are too broad or otherwise unwarranted.

Companies should be flexible with respect to the public domain question. Whether the traditional knowledge 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 traditional knowledge that is secret or not widely known more than traditional knowledge that can (with some effort) also be retrieved from generally accessible sources.³²

Companies agree, in any case, to reward and to compensate the use of traditional knowledge disclosed to them. Companies can consider any type of benefit sharing the indigenous partners wish. Benefit sharing may also include non-monetary measures not directly related to the use and commercial exploitation of the traditional knowledge, which strengthen the

autonomy and development of indigenous communities.

In a business framework, companies must measure the accumulated amount of all benefits to be paid against the economic value they assign to traditional knowledge. 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 benefit sharing agreements may become viable.

Companies take the broader social and political concerns of indigenous partners into account wherever this is compatible with the negotiated subject matter.

What companies should do outside contractual relationships

Companies must comply with existing regulations (international and national) for access to traditional knowledge. 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.

Companies should not seek access to, or use, traditional knowledge that

is clearly identifiable as the knowledge of an existing indigenous community (or individuals from such a community), without prior informed consent.

Traditional knowledge 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) traditional knowledge should be considered as the 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.³²

Companies should not be obliged to seek prior informed consent 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.

Companies should accept that traditional knowledge 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.

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 traditional knowledge 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 traditional knowledge that has

only been disclosed in ethnographic (ethno-botanical, etc.) descriptions. Companies acknowledge the proposition of the European Chemical Industry Council (CEFIC) that special (*sui generis*) legal systems might be devised that protect traditional knowledge – even when it has already been widely published or known outside the communities – under certain circumstances in favor of the holders of such knowledge.

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” traditional knowledge. Accordingly, companies should refrain from any such uses. On the other hand,³⁴ concepts of sacredness are culture-bound. Traditional knowledge 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.

³² One participant (NGO) wanted to add the following statement: “Companies might commit themselves [to not] seek access to traditional knowledge-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 traditional knowledge 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 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.

Protection of traditional knowledge

and the legitimate interests of its holders in the broader context

Companies acknowledge that the fair and equitable use of traditional knowledge 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.

Indigenous communities should acknowledge that negotiations with business companies over access to traditional knowledge 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.

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.

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 traditional knowledge.

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 prior informed consent, declaration of origin, and ABS agreements when it comes to the granting of patents).

Equally, they should 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.

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.

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 traditional knowledge 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.

A photograph of a young child looking upwards with their mouth slightly open, as if receiving a drop of medicine. A hand is holding a glass medicine dropper with a red liquid inside, positioned directly above the child's mouth. The entire image is overlaid with a semi-transparent teal color.

Access to essential medicines

Lack of access to essential medicines is an element in the health crisis that threatens many countries in the poorer parts of the world. Access to medicines is affected by many factors, intellectual property rights (especially patents) being one of those factors. In this respect, a broad consensus exists among representatives of the most different organizations.

Controversial issues are the extent to which patents affect access to medicines and whether such impact warrants (or requires) the revision of current regimes of intellectual property, especially of the TRIPS Agreement.

The assessment of the relevance of patents has a factual dimension and a normative one.

In the factual dimension the crucial question is whether patents, because they lead to higher prices, will make essential medicines unaffordable for poor people. It was understood that any discussion of this question must also touch upon the safeguards - such as compulsory license or parallel imports - built into intellectual property rights (IPR) regimes to mitigate possible negative impacts of patents on access to medicines.

The participants discussed how these safeguards could be used (and redesigned) under the TRIPS Agreement. In principle, conceptions could range from denying patents for medicines altogether to making even stronger provisions for IPR protection (TRIPS-plus). Some participants also referred to supplemental strategies that might function as equivalents to those safeguards: differential pricing, donations, etc. Some of these strategies (international funds, new health policies) require interventions from the public sector (governments or WHO).

In the normative dimension the discussions focused on three main questions:

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

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

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

The conclusions listed below for the working group on access to essential medicines hardly represent perfect consensus. The London conference succeeded in passing a series of statements that came very close to unanimity (footnoted as “London”).

However, often the best result achieved consisted in statements that attracted many, but not all, participants. Such statements, especially because they are supported by representatives from

both the industry and the NGOs, indicate “attractors of argumentation”. They should be included in the conclusions to give a more complete picture of the whole field of argumentation.³⁵



The need to integrate conflicting objectives and values

The following three statements taken together suggest that a workable compromise is at stake in the whole debate. The statements acknowledge in principle the goals and values of the conflicting parties, establish the primacy of public health in the case of conflict, and restrict the possible interpretation of “primacy” in such a way that industry does not have to pay the whole bill.

Not all participants, but many with otherwise opposing views, supported the balance represented by the following three statements in combination. The “in combination” has to be emphasized especially in this section because each of the three statements taken in isolation would be misleading as a representation of the discussion.

Any sustainable solution to the conflict between IPRs and access to medicines should combine respect for human rights, the acknowledgement of property rights, and it should be compatible with R&D.³⁵

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

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

³⁵ One participant found section A, “The need to integrate conflicting objectives and values”, unbalanced and preferred to remain “observer”, saying neither “yes” nor “no”.

³⁶ One participant (expert) preferred the following wording: “Any sustainable solution... should combine respect for human rights with a recognition that there is a need to provide public support and private incentives to fund R&D of new medicines.” This statement was opposed by another participant if not combined with the following statement: “If there is a conflict, public health has primacy over IPRs.” One may say that it was adopted in London with one qualification; there was no unanimity, but the combination of this statement and the

sentence above was acceptable to many representatives of opposing views.

³⁷ This statement was opposed by some participants, because “one human right cannot prevail over the other”. One participant (industry) emphasized that the statement does not imply “that any public health issue is enough to override IPRs ... [rather:] if serious problems arise and no sustainable solutions have been found through public spending, donations, etc., then, of course, public health has primacy over IPRs and waivers could be implemented to safeguard that poor people still have access to essential medicines. But this should be the ultimate solution.”

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

The role of patents, prices, and R&D

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

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

The main causes of the global health crises are widespread poverty,

inadequate political priorities and the inability/failure of states and of the international community to provide public funding, especially for those populations that cannot even afford to buy generics.

The outcome of the Doha Declaration is endorsed “as it stands”.⁴⁰

A combination of safeguards, essentially in the form of compulsory licensing, with a system of differential pricing⁴¹ would be a significant improvement in the status quo. In a differential pricing system, least developed countries would have access to essential medicines at cost prices or below (drug donations).⁴²

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

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

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

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

³⁹ Agreed upon at the London conference.

⁴⁰ Agreed upon at the London conference.

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

⁴² One participant (expert) preferred the formulation “... or below” to be deleted, since drug donations are unrelated to pricing issues. Another participant disagreed with the whole paragraph, because “there is no consensus that compulsory licenses are linked with the

use of differential pricing.” In addition, the same participant stated that differential pricing schemes will not improve access to essential medicines, because other factors are much more relevant in this regard.” Another participant (industry) pointed out that a scheme of differential pricing should not prevent the search for individual, possibly better, solutions.

⁴³ One participant preferred the following formulation: “Parallel imports and differential pricing may require stronger controls in developed countries to avoid diversion of products from low-priced developing countries’

markets and a renunciation of referential pricing by developed countries’ governments.

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

⁴⁵ Agreed upon at the London conference.

⁴⁶ Agreed upon at the London conference.



Human rights and justice

Human rights and IPRs

There was a broad consensus that companies have a moral duty to help those in need, and to promote better access to medicines for the poor. Participants did not agree, however, that such a duty could be framed in terms of human rights. As a legal document, the Declaration of Human Rights obliges states, not private companies.

There was consensus that the right to healthcare obliges governments, for example, to set policy priorities that support access to medicines, including appropriate funding of healthcare systems, or to use the safeguards and flexibilities of patent law accordingly. These obligations do not necessarily imply a mandate to disregard the protection of private property, since the latter is a human right as well.⁴⁷ Companies, in turn, have a duty not to undermine legitimate government policies for better access to medicines.

Public healthcare is primarily the responsibility of the government.⁴⁸

Governments have the right to define “emergency” and a duty to act upon it, e.g., by allocating appropriate

funding, giving primacy to public health, setting the right priorities.⁴⁹

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

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

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

Debate over the justice of TRIPS

The justice of the TRIPS agreement, both in the sense of the fairness of

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

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

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

The whole IPR system discriminates against poor countries⁵² and small inventors because it is too costly.

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

⁴⁸ Agreed upon at the London conference.

⁴⁹ Agreed upon at the London conference.

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

⁵¹ Some representatives of industry said that this point should be deleted for the following reason: “It is the other way round... GATT... if

implemented correctly... would result in advantages for both developed and developing countries. Only because the USA and the EU have not yet done this in the agricultural and textile sector, developing countries are still behind.”

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

Appendix

Participants in the dialogue

Argumedo, Alejandro	Indigenous People's Biodiversity Network
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Hvid, Nina	Roche
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Karol, Robin	DuPont
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* Discontinued his participation after the first conference.

** Participated in working group II, but does not endorse the outcome of this group. He neither endorses nor opposes the results of the other working groups.

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*** Participant requested that his organization be listed with the following qualifier: "The CRG participated in the dialogue, and neither endorses nor opposes the final report and other distributed documents."

Disclaimer

The views expressed by the participants in the dialogue process should help the reflection and discussions around the issue of intellectual property rights. This report is neither a position of the WBCSD nor of its members.

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