



Ensuring Policy Options for Affordable Access to Essential Medicines

Conclusions of the Dialogue

**Bellagio, Italy
(12 to 16 Oct. 2004)**

Introduction

1. The UNCTAD-ICTSD Project on Intellectual Property Rights (IPRs) and Development has organized since October 2002, under the auspices of the Rockefeller Foundation, a series of dialogues in response to concerns that continuing trends in the formulation of international intellectual property policies may be detrimental to economic, technological, social, and cultural development as well as poverty eradication¹. One important outcome of the first dialogue was the launching of the *Frati Initiative* with the view of initiating a process of follow-up and monitoring to the ideas and suggestions made during the dialogues.

2. The *Series* has gathered a diverse group of specialists, government experts and members of international and non-governmental organizations that meet in their personal capacity to assess current international trends related to intellectual property and development. They are aimed at strategic discussions and the identification of concrete recommendations that could contribute to the formulation of development-oriented policies. Three Dialogues have been organized since 2002.

3. The October 2004 Dialogue included participants from the policy-making community, negotiators, capital-based officials, intergovernmental organizations, the private sector, public health sector, academia and civil society organizations. It discussed the following:

- Latest developments and trends on IP and health;
- Current efforts to develop Public-Private Partnerships (PPP) as to engage in wider R&D for neglected diseases;
- Approaches to facilitate access to medicines through compulsory licensing;
- Creating and promoting domestic drug manufacturing capacities: legal and economic feasibility assessment;
- Competition policy as a tool to address public health concerns.

¹ See <http://www.iprsonline.org/unctadictsd/description.htm>

5. The participants acknowledged the importance of analysis and public debate on intellectual property and other related issues relevant for ensuring access to essential medicines and suggested that governments have a broad set of tools available that could be used to ensure access to essential medicines.² These tools not only relate to the field of intellectual property but also include investment, industrial, health and competition policies. The options available under all these policies should be explored further so as to allow governments to address different situations and problems that may vary according to different levels of development. In the tradition of these dialogues and with the view of contributing to the advancement of development-oriented policies, the group identified main challenges and actions that might be further required apart from the possible policy research gaps.

6. The deliberations focused on two areas dealing broadly with issues related to manufacturing capabilities and access to technologies, and to compulsory licensing and competition policy.

Manufacturing Capabilities and Access to Technologies

Challenges

7. Countries are currently facing various barriers to access medicines at affordable prices. One relates to the lack of reliable providers of manufactured drugs. Trying to decide whether to continue to rely on import (and use CL and competition policy to drive down prices) and/or whether to develop their own manufacturing capacity is one decision that countries need to carefully weigh before engaging in the design and implementation of drug import or manufacturing policies.

8. In the case of setting manufacturing capacities countries need to weigh a wide range of complex factors including international markets, trade policies, economic/investment instruments, distribution channels, safety regulations and IP management, in order to design and facilitate appropriate policies. Solutions need to be tailored to individual country situations and implemented accordingly.

9. In this context, a special challenge is offered by the Least Developed Countries (LDCs), since it is more difficult for them to get the advice and expertise that is required to take informed decisions on creating local manufacturing capacity, increasing access to technology and improving conditions for technology absorption capacity in the local contexts. The implementation period of the TRIPS agreement and of the Doha Declaration could assist generating an incentive for investment in local manufacturing capacities but is not the only factor.

Actions

10. Participants identified the following actions:

² The report of the meeting is contained in a separate document.

- To develop instruments ("toolkits", manuals, or handbooks) for assessing options and opportunities to create local manufacturing capacities, improving technological absorption capacity and access to technology in the pharmaceutical sector. These instruments should be based on both external factors and domestic conditions, thereby enabling developing countries to assess their policy choices in a realistic way; and aim at clarifying the terms and conditions for improving manufacturing capacities and access to technologies, and provide a breakdown of accompanying concepts and factors, in order to make them more transparent and detailed. They should also provide a clear set of assessment indicators to developing countries and LDCs that would pave the way for a more accurate examination of policy choices in these areas, as well as the costs and benefits of particular choices over others and support needed in implementing their chosen strategies;
- To strive for coordinating policies in the area of manufacturing capacities and access to technologies with their trade policy decisions in general, and trade negotiations in particular. This process should be embedded in country-specific intellectual property policies and activities;
- To encourage self-initiated and pro-active strategies in accessing technologies. There is greater need for developing countries to increase their capacity of technology absorption. National policies should include, but not be limited to, or only rely on, the technology transfer provisions under the TRIPS Agreement and other international commitments. National policies should also focus on what countries can do (host country measures), in order to create a suitable environment for allowing access to medicines and increase technological absorption in local contexts.

Policy Research Gaps

11. Participants identified the following main policy research gaps:

- To analyze and compare cases of success and failure in creating and promoting local manufacturing capacities in the pharmaceutical sector. Some of the cases that could be analyzed include Italy, Spain, Colombia and Bangladesh. Experiences of UNIDO, World Bank and other international agencies in this area could be relevant in undertaking this activity;
- To identify relevant factors leading to the build-up of R&D capacities in developing countries and the challenges in making them work in other LDCs;
- To explore different modalities of public-private collaboration including PPPs, in promoting access to knowledge and technological absorptive capacity;
- To document technology transfer initiatives and activities in the pharmaceutical area. UNCTAD experience in the area could be relevant in undertaking this work;
- To create more coherent research frameworks, information resources and databases in the areas of developing manufacturing capacity and access to technologies and linking these to trade and health policies.

Compulsory licensing and competition policy in ensuring access to essential medicines

Challenges

12. Participants identified the following challenges with regard to the role of compulsory licenses and competition policy in ensuring access to essential medicines:

- To assess the impact of Free Trade Agreements (FTAs) on access to essential medicines including the issue of data exclusivity. Here, a distinction should be made between countries that have already signed FTAs and those that are yet to sign. In the case of those that have already signed, ways to mitigate the impact of the FTAs should be explored;
- To examine the viability of alternative innovation and research strategies, both at the national and international levels. For example, the R&D treaty initiative being discussed by the NGO community;
- To explore possible ways of using competition policy to increase access to medicines, without affecting the incentives to innovate;
- To examine the goals of competition policy and the inter-relationship between intellectual property and competition policy;
- To create awareness about the potential of competition policy in curbing the abuse of intellectual property rights, and to design a positive proactive agenda at the national, regional and multilateral arenas;
- To work out practical parameters and policy limitations in the use of compulsory licensing;
- To create a favorable environment for the production and consumption of generic products, especially after 2005;
- To foster the domestic implementation of the various regulatory tools in the areas of health and intellectual property and to assess their relative utility within the context of specific countries;
- To ensure the coherence of the various policy instruments at the national/international level that are/can be used in promoting access. Specifically by connecting the TRIPS flexibilities to the broad access movement including issues pertaining to sustainable innovation, funding, and human rights.

Actions

13. Participants identified the following actions in order to ensure access to essential medicines:

- To frame the access debate as a universal consumer issue in order to align the interests of North-South consumers (within this, the creation of North-South coalitions could be an important means);
- To engage in and evaluate whether or not it is appropriate to have a trade framework for R&D at the international level;
- To develop a more sophisticated campaign to address access issues arising in FTA's, including issues of data exclusivity provisions and its impact;
- To document and widely disseminate potential tools (including methodologies) available to increase access to medicines, including the experiences of developing countries that have used some such tools (i.e. South Africa);
- To use the practical experience of civil society actors at all levels of policy making and capacity building activities, including technical assistance;

- To prepare a comparative report on the implementation of the Doha Declaration by countries, both developed and developing ones;
- To assess the extent of technical assistance provided by international institutions and developed countries on the implementation of the 30 August 2003 Decision;
- To examine the intellectual property policies in various types of PPPs to assess the extent to which intellectual property issues hinder or assist progress in such PPPs;
- To explore ways in which PPP's can be made more transparent, making them accountable to not only to their funding organizations, but also to the public at large;
- To design and implement effective mechanisms and practices to control anti-competitive practices;
- To encourage countries to cooperate in producing and supplying generics in post-2005, including adequate planning to ensure a sufficiently large market;

Policy Research Gaps

14. Participants identified the following to be the main policy research gaps:

- To collect data on the generic industry and alternate plans to deal with the emerging situation in developing countries post-2005;
- To evaluate the impact of new trends in data exclusivity on access to medicines and to explore the impact of alternate models to exclusive rights;
- To explore the relationship between the various regulatory tools for ensuring access to medicines and assess the comparative feasibility of each tool in specific local contexts;
- To explore how competition policy can be used proactively to encourage innovation;
- To assess the impact of intellectual property rights and pricing provisions in trade agreements and determine if they could undermine consumer protection and access to medicines in the North;
- To compile the experience of developed countries in using compulsory licenses (both case law and practice), to explore further the relationship between competition law and intellectual property;
- To estimate indicators for determining affordable prices according to income levels in each country. These could serve as easy reference points while invoking compulsory licensing on grounds of excessive pricing.