



Fostering R&D and Promoting Access to Medicines

Programme

Bellagio, Italy 22-26 October 2007

Background

As part of the Rockefeller Foundation's Frati Series on Intellectual Property (IP) Policies and Development, ICTSD organised a series of meetings at the Bellagio Study and Conference Center between 2002 and 2005. The series responded recent trends in IP policymaking posing challenges to the economic, technological, social and cultural development of developing countries. It mobilised a diverse group of specialists, government experts and members of international and non-governmental organisations to identify strategic objectives, explore innovative policy approaches and contribute to the design of pro-development and pro-competitive IP initiatives.

Since then, ICTSD has engaged in research aimed at building knowledge on new developments in IP policy and published several issue papers and an array of regional and country studies. These have illuminated changes in the global economy and political context. This work has resulted in ICTSD refining its strategy to focus more explicitly on the underlying purpose of IP- to promote innovation and creativity- for all countries, not just those with the resources and policy infrastructure needed to make IP workable.

In this context, ICTSD's objective is to create new opportunities for the world's poor and vulnerable populations by fostering an environment in developing countries that is more conducive to innovation, creativity, as well as technology transfer, dissemination, and absorption. In addition, ICTSD endeavours to create a more balanced system that protects public interest, including access to medicines and educational materials.

Bellagio 2007- Fostering R&D and Promoting Access to Medicines

For several years now, the World Health Organisation (WHO) has undertaken efforts aimed at solving the health and IP puzzle. In 2003, WHO launched the Commission on Intellectual Property Rights Innovation and Public Health (CIPIH) to examine appropriate funding and incentive mechanisms for the creation of new medicines for diseases that disproportionately affect developing countries. The CIPIH issued its final report in 2006, which included sixty recommendations relating to drug discovery, development, and delivery. Since then the World Health Assembly has set up an Intergovernmental Working Group (IGWG) to draw up a plan of action based upon the recommendations of the CIPIH report. The IGWG convened its first meeting in December 2006. It is scheduled to meet again in November 2007.

The CIPIH report covered a broad canvas and reviewed many different proposals for fostering R&D and promoting access. However it did not manage to produce a concrete set of policy proposals on which all members of the Commission could agree. That is now the task of the IGWG.

Moreover, the World Trade Organization (WTO) has grappled with the challenge of balancing intellectual property rights and public health since the creation of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Actual implementation of the Agreement might constrain generic production and raise concerns about the supply of affordable medicines in the world. Its implementation has led to several legal disputes over the use of legal flexibilities in the TRIPS agreement. Additionally, countries have responded by issuing compulsory licenses for the generic production of patented medicines. In the context of international trade, these challenges have been further exacerbated by the number of free trade agreements with more stringent intellectual property obligations than those contained in the TRIPS. These ‘TRIPS-Plus’ provisions might ultimately delay or limit the entry of generic competition.

Objectives

The purpose of this dialogue is to consider in a small group of stakeholders a number of specific policy proposals in greater detail which would address, and reconcile, the objective of bolstering both innovation and access. It will bring a number of new voices to the table with those of seasoned experts and practitioners to ‘crack open’ the proposals, identify the opportunities and drawbacks associated with each, and identify various components that might ultimately be brought together and operationalised to foster R&D and promote access. A common underlying theme is the need to allocate the costs of R&D fairly while promoting access to medicines. If common ground can be located around one or more such proposals, with the active support of participants, this could be influential in respect of future deliberations.

The proposals to be considered include:

- The Prize Fund Model
- Patent Pools
- Advanced Market Commitments
- New forms of research and development funding
- Maximising flexibilities in the current patent system

Methodology

The meeting will be structured around specific proposals that are mentioned in the draft strategy and plan of action developed by the IGWG. Emphasis will be given to interactive discussions between participants, who are invited in their personal capacities. Each section will have one or two resource persons who will introduce the main theme in approximately 15-20 minutes and discussants to comment on the proposals in approximately 5 minutes. PowerPoint facilities will be available during each of the sessions. To support this process ‘think pieces’ will be made available on some of the topics. All participants are invited to actively participate in the discussions and are encouraged to make practical recommendations on how to move the agenda forward. Each session will have a facilitator to steer the debate to precise conclusions. A

rapporteur will be responsible for distilling the main points and conclusions of the debate. The final report will be the responsibility of ICTSD. The report will be a non-attributed document that will be circulated among participants for comments before being made available to the general public at the website www.iprsonline.org. The issues to be addressed by the dialogue are diverse. However, in bringing together a number of actors with a range of backgrounds and knowledge - but who share a common vision of fostering R&D and promoting access to medicines- the dialogue will seek to explore and benefit from synergies between different areas of expertise. The meetings will start at 8.30h each morning and end at 19h each evening, followed by dinner. There will be lunch breaks from 12.30h to 15h. These breaks are intended to contribute to a better and more relaxed dialogue among participants and also to benefit of the excellent Bellagio facilities.

Tentative Programme

Monday 22 October 2007

- 19.30** Dinner
- 21.00-22:00** Welcome and introduction by the organizers

Tuesday 23 October

- 8.30-9.00** Opening of the Dialogue and presentation of participants
Ricardo Meléndez-Ortiz
- 9:00-12.30** **Introductory Session – Taking Stock**
- Facilitator:** Ricardo Meléndez-Ortiz
Resource Persons: Ellen 't Hoen and Carlos Correa
Discussant: Chutima Akaleephan

The introductory session will examine what has happened in the multilateral context on IP and health. It will track the history of the debate from the UK Commission on IP and the WHO CIPIH to the current IGWG process. Moreover, it will identify various proposals for bolstering R&D and improving access to medicines. Participants will be invited to address, among others, the following set of questions:

1. What progress has been made to date in advancing an international IP policy that is supportive of public health?
2. What are the main elements of the latest draft strategy and plan of action in the IGWG? What other elements should be included?
3. Which proposals on R&D financing and access could be most useful in addressing the two fundamental problems of providing medicines for diseases affecting the developing world and making them affordable?
4. Which proposals hold the greatest promise for being operationalised?

15.00-19.00 **Exploring New Paradigms for Health R&D**

Facilitator: Ambassador Alberto Dumont
Resource Persons: Aidan Hollis, James Love, Peter Brown
Discussant: Shaidah Asmall

This session will look at some initiatives aimed at providing economic incentives for innovation to combat some of the world's deadliest diseases. It will look specifically at Prize Funds, Advanced Market Commitments, the Medical R&D Treaty, and the International Finance Facility (IFF).

1. What are the various Prize and R&D Fund proposals?
2. What is the essential difference between a prize fund and an advanced market commitment?
3. What is the IFF and how can it operationalised?

4. What are the pertinent issues in implementing such mechanisms?
 - a. Level of funding
 - b. Sources
 - c. Relevant criteria
 - d. Administration
5. What should the relationship be to such mechanisms and the IP system?

Wednesday 24 October 2007

8.30-9.00 Summary and highlights of first day's deliberations

9.00-12.30 Maximising IP-Related Mechanisms

Facilitator: Francisco Rossi

Resource Persons: Warren Kaplan, Pedro Roffe, and David Vivas-Eugui

Discussant: Sudip Chaudhuri

This session will examine existing opportunities to improve access and promote innovation. It will examine how patent pools may be utilised to facilitate the production on medicines for developing countries. Additionally, it will examine current flexibilities in the patent system how they may be implemented and better utilised at the domestic level.

1. What are the various types of patent pools and what incentives do title holders have to contribute to a patent pool?
2. What are the issues surrounding implementation of a patent pool?
3. What steps can be taken to advance implementation of TRIPS flexibilities with regard to patents and test data protection?
4. What other mechanisms within the IP system can be used to bolster R&D and increase access?

15.00-19.00 Achieving Global Drug Access and Research

Facilitator: Ambassador Nicholas Thorne

Resource Person: John Barton

Discussants: Ron Marchant and Alberto Alvarez Saavedra

This session will explore opportunities for bolstering innovation and increasing access both within the WHO, as well as in other fora. It will explore the possibility of a sector-specific deal on pharmaceuticals and broach a number of issues, including regulatory barriers, differential pricing, and counterfeit drugs. Additionally, it will take up the issue of technical and political feasibility of all of the proposals under discussion and explore elements that might comprise an encompassing agenda on research and action for pharmaceutical innovation and access.

1. What are some of the potential components for a broader sector agreement in pharmaceuticals?
2. What are some of the potential costs and benefits for each set of stakeholders in such a sector agreement?
3. In light of all of the proposals under discussion, which proposals should be addressed within the context of the IGWG? Which ones should be addressed elsewhere? Where?

4. Which mechanisms are most likely to receive broad political support and engagement by all sectors?
5. Which mechanisms have already been applied at the national or regional level? What lessons can be learned?
6. What should be the role of international organisations (WHO, WTO, WIPO, UNDP, UNAIDS, UNITAID) in designing, establishing, and advancing such incentive mechanisms at the global and local level? What should be the role of other stakeholders, including developing countries?
7. How can we more effectively engage the private sector in these discussions, including pharmaceutical companies, the insurance sector, private distribution services, and private hospital services?

Thursday 25 October 2007

- 8.30 What have we accomplished so far: a summary of the first two days
- 9.30-16.30 The way forward: Working Groups
- 16.30-18.00 Conclusions