



Bellagio Dialogue on Ensuring Policy options for Affordable access to essential medicines MEETING REPORT

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

1. In October 2002 and September 2003, ICTSD and UNCTAD organized two dialogues entitled “*Towards Development-Oriented Policy*”: “*Setting an Agenda for the next Five Years*” and “*Advancing the Reform Agenda*”, as part of the Rockefeller Foundation’s Frati Series on Intellectual Property Policies and Development. This process mobilized Geneva-based negotiators, capital-based policy makers, NGOs and distinguished experts and aimed to identify strategic objectives, entry points and levers in the short, medium and long terms in IP negotiations and reform. It contributed to the design of a pro-development and pro-competitive IP agenda and to assess current trends in harmonization of IPR standards (WTO TRIPS Council, WIPO Patent Agenda, bilateral and regional agreements).

2. As a follow up to the work carried out over the last two years, the Rockefeller Foundation sponsored a focused dialogue on “*Policy Options for Ensuring Affordable Access to Essential Medicines*” in October 2004. The main objectives of the dialogue were to:

- Assess the latest developments and trends on the IP and health debate at the multilateral, regional and bilateral levels and discuss innovative ways to reconcile the need to promote innovation while ensuring affordable access to medicines (e.g., proposals for international schemes to promote R&D);
- Explore the effectiveness of current efforts by Public-Private Partnerships (PPP) to use and manage intellectual property in creative ways in the development of drugs and vaccines for diseases affecting poor segments of society in developing countries (e.g., dual market agreements);

- Suggest practical approaches in the use of compulsory licensing to facilitate affordable access to essential medicines pursuant to the Doha Declaration on TRIPS and Public Health, and design effective strategies for exporting and importing medicines manufactured under a compulsory license (CL);
- Assess the legal and economic feasibility of new proposals for the creation and/or promotion of domestic pharmaceutical manufacturing capacities in developing and least developed countries;
- Explore options for using competition policy in addressing public health concerns; and,
- Identify policy actions and a research agenda to propose ways to deal with the various issues analyzed during the dialogue.

Recent developments in IP and Health

3. While the pharmaceutical sector is already very concentrated at the international level, it is expected that this concentration will be reinforced from January 2005, with the lapse of the transition period for developing countries to comply with Articles 65 and 70 of the TRIPS Agreement. The cumulative impact of these changes cannot be predicted beforehand, since it depends on product patents on new products in addition to mailbox applications that have been awaiting the full entry into force of TRIPS. Broadly, the following inferences can be made. Firstly, the trend of consolidation in the pharmaceutical industry is likely to spill over to countries like India, which have prominent local generic industries, making an imminent hike in prices more likely. If this leads to price trends similar to what one sees in the USA and the European Union, finding low cost sources of drugs for disadvantaged populations only in developing countries may become more difficult. Secondly, free trade agreements (FTAs) will have a major impact on pharmaceutical prices and access to medicines due to new standards especially in the area of data protection¹. Thirdly, pharmaceutical consumption is increasing in both, developing and developed countries and costs associated with rising consumption are affecting access in developed countries, thereby burdening social security systems. Lastly, since USA bears the largest share of pharmaceutical R&D presently, other countries are coming under increasing pressure to share R&D costs with the USA. This, it is felt, will reduce free riding by other countries over the results of such R&D.

¹ Current clauses on data exclusivity in FTAs are very similar to the standards on data exclusivity in the United States (the US grants 5 years of data exclusivity). It was mentioned during the discussions in the meeting that Chile has found some leverage space on data exclusivity in the national implementation of its FTA with the US by limit its application only to new

4. In this context, the major issues are:

- How can we ensure that the flexibilities within the TRIPS Agreement are not undermined by FTA agreements?;
- How should developing countries deal with the question of data exclusivity in FTAs?;
- Can new international frameworks be designed to share cost and benefits from R&D in the health area?.

5. While addressing these issues, the importance of options available under the “regulatory toolbox” was also noted: these comprise of price control, patentability exceptions, compulsory license, data and competition policies. All these flexibilities are permitted by TRIPS and reinforced by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2). Undoubtedly, there is a need to ensure that these flexibilities are kept to meet the development and public health needs of developing and least developed countries. In this regard it was considered important to conclude an amendment process in the TRIPS Council in such a manner that could resolve problems of countries without manufacturing capacities without imposing burdensome excessive procedures such as the ones established by the 30 August 2003 Decision. Participants considered that the main factors that affected developing countries’ abilities to still make use of the Doha Declaration and the 30 August 2003, included burdensome procedures, lack of legal reform at national level, bilateral pressures, lack; new tendencies in bilateral on data exclusivity, etc.

6. Various participants also indicated that current models for promoting R&D for pharmaceutical innovation, such as the patent system, were not meeting their essential mission, especially in the case of neglected diseases. For example, out of the 1233 drugs generated between 1995 and 1997, only 13 could be used to treat tropical diseases. This means that the current use of patents as an incentive to R&D has not delivered innovative new medical solutions for diseases and illnesses that affect poor countries. Thus, there was a need for examining alternative models including the role of private-public partnerships and new proposals for promoting R&D in health that call for a rethinking on how to allocate the burden of R&D costs in health.

chemical entities. This is similar to what is being contemplated in India (See Hepburn, 2004) and the flexibility this offers needs to be explored further.

Module 1: Explore the effects of current efforts to develop Public-Private Partnerships (PPP) to accelerate R&D for neglected diseases

7. Various initiatives are underway to promote partnerships between private sector product developers, developed and developing country researchers and public health officials that would broker deals around efforts to invest in R&D for diseases of the poor. These product development PPPs are gaining extensive experience in the relationship between R&D and IP, on IP's role as both an incentive and barrier to access, as well as other barriers to access. There are four different kinds of PPPs in health presently from which lessons can be drawn: product development partnerships, partnerships to improved access to mechanisms, global coordinating and financing mechanisms and partnerships for strengthening health systems (such as those funded by the African Comprehensive HIV/AIDS Partnerships between the Botswana Government, the Gates Foundation and Merck). Most of experience in IP management or negotiation rests with the product development partnerships.

8. It was agreed by participants that one of the main challenges to the designers of recent international policy initiatives like the R&D treaty is to better reflect the experiences of the PPPs. It was also felt that distinguishing between global PPPs and other PPPs for R&D is important to see potential future trends and to measure effects of such undertakings. Specifically, it was recognized that the role of PPPs went beyond merely creating new products. PPPs also act as advocates addressing the growing inequality in access to pharmaceuticals and the need to focus on innovation needs of developing countries. They can play an active role in promoting changes in local R&D in both the public and private sector in developing countries. Therefore, how PPPs can play a role in increasing local R&D through IPRs and other forms of inter-organizational learning needs to be looked at in greater detail. It was also acknowledged that although PPPs view the issue of building local capacity in the South very positively, there is more that PPPs can do to enable Southern countries to meet their own innovation needs. On this point, a great deal of emphasis was laid upon drawing lessons from PPPs' experiences and their role in promoting innovation in order to influence international policy-related developments on innovation policies for developing countries.

9. While there are potential roles for global product development PPPs, it was emphasized that currently most of such ventures are relatively recent, that they operate in industrialized countries (except for clinical trials) and that their experience to date is concerned with negotiations needed to secure options to developed candidate products, which might be subject to patents held by third parties. The experience of product development PPPs is mostly limited to managing IPRs arising

from their investment and on negotiating “access conditions” for background IP. However serious considerations should be given to how existing global product development PPPs could share their experience with IP management and thus strengthening emerging R&D efforts in developing countries.

Module II: Approaches to facilitate access to medicines through compulsory licensing

10. This module explored concrete proposals and case studies on how CL could enhance local production, export and distribution of essential medicines at affordable prices in developing countries with and without manufacturing capacity, with a particular emphasis on paragraph 6 of the Doha Declaration. The experiences of various countries, such as, Malaysia, Mozambique, Zambia, Swaziland, Kenya, Uganda and Cameroon, were contrasted. Concrete methods to set remuneration based on income levels of countries were proposed.

11. The discussion underscored the important role that CL could play in reducing prices and increasing access to new medicines. CL or simply the threat of CL has proven to be a very effective price-mitigating instrument – a good example of this is the Brazilian negotiations on HIV/ AIDs drugs. It was agreed that there is need to facilitate more specific approaches on CL, since at present there is a lot of confusion on who can request CL, who can grant CL, how cost-effective it can be, among other procedural details. All participants felt that setting clear national procedures are very important to obtain CLs or to litigate for them, when the need arises. Therefore, strengthening local actors (governments, generic industry, consumers, civil society) should be a focal point of strategies and technical assistance efforts. The three main issues that should be explored further are:

- How can anti-competitive practices be used as a sound basis for the grant of CL?;
- Can there be regional initiatives to tackle CL?; and,
- How can procedures for CL be designed or facilitated?

12. A lot of concern was expressed on TRIPS-Plus Agreements that mandate data exclusivity requirements that go well beyond Article 39, and how this may affect regulatory approval of generics even when a compulsory license for the said product was to be obtained. It was agreed that more awareness needs to be created amongst developing countries on how to deal with data exclusivity clauses in FTAs and TRIPS-Plus agreements and their practical implications for public health issues.

Module III: Creating and promoting domestic drug manufacturing capacities: legal and economic assessment

13. During this module two main issues were addressed by participants: (a) the structure of the pharmaceutical market after 2005 and (b) the issue of promoting local manufacturing capacity. The first part of the module focused on the market structure after 2005 when all developing countries (excluding LDCs) are required to comply fully with the TRIPS Agreement. The difficulty of assessing and quantifying the effects that are likely to arise after the introduction of product patents in pharmaceutical and agrochemicals in various developing countries was noted, particularly due to the lack of substantial studies in this area. A large volume of the current exports of bulk drugs by many generic and brand producers will cease after 2005 when regular generic suppliers such as India and China will have to comply with TRIPS. Many participants expressed concern about the ramifications of this on price competition and drug availability in other developing countries, since only a few developing countries such as India, China and Thailand have the capacity to produce certain types of bulk generic drugs.

14. The key issue for developing countries post-2005 could be summarised as the “*make or buy*” dilemma. In this regard, the findings of Kaplan² and Laing seem pertinent. They warn that it makes little economic sense to produce medicines domestically in many parts of the world, due to problems of economies of scale. This is corroborated by the present situation where the ability to locally manufacture and to comply with quality standards in developing countries is either limited or very low. The local sector is also not often reliable or not well advised or efficient enough to offer competitive production.

15. It was felt that developing countries that wish to set up manufacturing facilities should evaluate various factors to make sound economic decisions. These factors could include the following, among others:

- Legal opportunities given by the 30 August TRIPS Council Decision;
- Opportunities for investment;
- Opportunities for import substitution;
- Extent of specialization in the local pharmaceutical sector;

² Among the factors of competitiveness in the pharmaceutical sector identified by Kaplan we could include the following: GDP higher of 100 billion, population over 100 million, and competitiveness indicators according to UNIDO.

- Specific protection measures for emerging industries, especially pharmaceuticals;
- Creation of domestic manufacturing capacities;
- Opportunity costs of places resources in this sector;
- Costs of adopting new standards;
- Adequate supply of raw materials; and,
- Technology transfer and technology absorption capacities.

16. It was acknowledged that creation of local manufacturing capabilities could be done by a variety of means including enhancing already existing capabilities, technology transfer and even public production (which seems to have worked well in the case of India, China, Egypt and Cuba). A classic example of an LDC that has developed its own manufacturing capabilities in a sustainable way is Bangladesh, which kick started this through a 1982 national drug policy. Local drug companies in Bangladesh currently export to a number of other countries, particularly African countries such as Tanzania and Libya. However Bangladesh still needs considerable help in procuring access to Western markets, especially on the issue of compliance to quality standards.

17. Participants noted that creating or enhancing local manufacturing capabilities is only one of the many available tools to enhance access to medicines in LDCs. Other complementary strategies are needed, such as purchasing and negotiating power at the regional level (pooled procurement). In this regard, the need to maintain long term and good relations with suppliers was highlighted. The desirability of smaller countries joining together and creating better economies of scale and even multi-country negotiation strategies was flagged up (with the “Brazilian model” and COMESA serving as good examples).

18. Finally, participants stressed upon the need to integrate industrial policies that aim at economic development with health policies within countries preferably in a way that creates incentives so that diseases of the poor are addressed. Links between various ministries and departments that dealt with these cross-cutting themes are required to promote a holistic approach and to enable coherent policy making in the area of public health. In the final analysis, it was also felt that strategies involving a separation of innovation (R&D) in the health sector and issues of creating manufacturing capacities might be a better alternative to the present system.

Module IV: Competition policy as a tool to address public health concerns

19. The key focus was to assess the feasibility of using competition policy to address the access to medicines issue. A note of caution was expressed that the focus ought not to be so much on competition law as much as competition policy itself, which is a much broader concept and encompasses industrial policy and market reform issues. Specifically, participants stressed the importance of using existing regulatory instruments to strengthen competition policy elements instead of embarking upon the creation of wholly new competition law frameworks that may involve extensive costs.

20. It was noted that a good starting point in this exercise is to examine the degree of flexibility inherent in the TRIPS Agreement for using competition policy instruments to advance public health issues. A simple reading of some of the main Articles of the TRIPS Agreement, including Articles 8, 31 and 40 seem to suggest a considerable degree of flexibility regarding the use of competition policy. However, the extent and ways in which this flexibility can be harnessed needs to be worked out in greater detail. The South African case is an excellent illustration of how competition law could be used in a creative way to reduce costs of and enhance access to essential medicines by threatening the use of compulsory licensing of patented products (in this case, AIDS drugs). At the same time, participants stressed the limitations of competition policy. It is only one of the instruments available among the various regulatory tools to enhance access, encourage coherence and engagement for profit drug makers including generic producers.

21. The consolidation in the pharmaceutical and chemical sector globally seems to be a trend of larger profits through reduced competition and not one of increased R&D investments. The resulting market structure affects static and dynamic competition in the market, especially because of increased possibilities of abuse of dominant market positions. Therefore, quite apart from studying the flexibilities available to developing countries in designing competition policies, participants agreed that it is very important to also look at the role of competition policy in reducing anti-competitive practices that may result from reasons other than stronger IPRs.

22. Finally, participants called for increased co-operation in the enforcement of competition policy, which could perhaps reduce costs normally associated with the implementation of antitrust rules.