



Fostering R&D and Promoting Access to Medicines

An ICTSD Series on New Opportunities Through Innovation

MEETING REPORT

**Bellagio, Italy
(22 to 26 October 2007)**

I. The background

1. 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 to 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.

2. 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.

3. 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.

4. The dialogue gathered a small, diverse group of specialists, government experts and members of international and non-governmental organisations that met, in their personal capacity, to discuss a number of specific policy proposals in greater detail which would address, and reconcile, the objective of bolstering both health innovation and access to medicines. It brought 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. A common underlying theme was the need to allocate the costs of R&D fairly while promoting access to medicines. The proposals included:

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

5. The 2007 dialogue was organized in four inter-related sessions, covering the following themes:

- Introductory session on taking stock of developments in IP and health;
- Exploring New Paradigms for Health R&D;
- Maximising IP-Related Mechanisms;
- Achieving Global Drug Access and Research.

II. Taking stock of developments in IP and health

6. Participants tracked IP and health developments from the introduction of the first essential medicines list by WHO in 1975 to the first time IP was raised in the context of the World Health Assembly and continuing through to the 2001 Doha Declaration on TRIPS and Public Health, the 2002 Report of the UK Commission on IPRs, the WHO Commission on IP, Innovation and Public Health (CIPIH), and finally the Inter-governmental Working Group (IGWG) on Public Health, Innovation, and IP. They also highlighted several resolutions of the World Health Organisation, such as those calling for:

- member states to *explore and review options under international agreements, including trade agreements, to safeguard access to essential drugs* (WHA 52.38);
- the establishment of the IGWG and its mandate to draw up a global strategy and plan of action aimed at, among other things, *securing an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries* (WHA59.24); and
- the development of proposals for *health-needs driven research and development for discussion at the IGWG that includes a range of incentive mechanisms including also addressing the linkage between the cost of research and development and the price of medicines, vaccines, diagnostic kits and other health-care products*(WHA60.30).

7. Much progress has been made in advancing a pro-health agenda in the context of discussion on trade and intellectual property. For example the Doha Declaration on TRIPS and Public Health contributed to: the adoption of the 2003 decision on the export of medicines for countries without manufacturing capacity; free trade agreements (FTAs) that do not limit compulsory licensing and parallel importation; recent changes in US policy on IP provisions in FTAs. The recently adopted WIPO Development Agenda aims to stop the push for IP overprotection and make the system more supportive of development. Finally, there has been a consolidation of new paradigms about IP. For example, several scholars, including two Nobel Prize winners, are looking at how to make IP supportive of development and NGOs are also contributing to research and analysis and tackling more difficult issues.

8. Participants outlined several mechanisms for fostering research and development, noting some of the advantages and drawbacks of each. Each of the mechanisms are designed to address different sets of problems and some of the mechanisms are more likely to incentivize investment in R&D in developed, rather than in developing countries.

9. Participants noted that the latest draft strategy and plan of action does not fulfill the mandate of the World Health Assembly. Moreover, proposals which de-link the cost of R&D from the price of products could be most useful in addressing the two fundamental problems of providing medicines for diseases which disproportionately affect developing countries and making them affordable.

10. Participants engaged in exchange of views over a myriad of relevant related questions, including:

- Who drives the current WHO process- governments? The secretariat? How to better ensure synergies between different international organizations (e.g., WHO, WTO and WIPO)? Should there be a special high representative of the UN Secretary General to monitor and guide the process?
- The role of the innovate sector and the importance of venture capital to spur innovation including the role of innovators and entrepreneurs in the South that is often disregarded in international deliberations.
- The scope of diseases outlined in the draft global strategy.
- The sustainability of the pharmaceutical industry in developed countries and the extent to which IP is working in developed countries.
- The assumption that IP is necessary for innovation.
- How regional R&D centres might be established and what they should do to ensure equitable partnerships.
- The capacity of governments to participate effectively in the IGWG.
- The importance of competition in bringing prices down.
- How countries might be able to subsidize R&D under the WTO rules.
- Potential benefits and drawbacks of a global database on IP.

III. Exploring New Paradigms in Health R&D

11. The Prize Fund Model would provide rewards for R&D in pharmaceuticals, particularly for those products needed in developing countries. It could serve as an alternative or a supplement to intellectual property rights. Participants explored three types of prizes, namely:

- Prize Fund Model proposed by US Senator Sanders (I-VT), which would substitute patent exclusivity with fixed prices based on therapeutical benefits;
- Advanced Market Commitments (AMCs), which provide incentives for commercialisation of specific vaccines;
- Comprehensive AMCs, which proposes an optional alternative to patent exclusivity, where payment is based on measured impact.

12. Participants examined the advantages and disadvantages of each, which related to issues such as, the alignment of incentives with medical need, relationship to existing patent system, how to assess therapeutical impact, and the pre-specification of technical standards. Discussion centred on several topics including:

- How a prize system might account for the varying prices of medicines in different countries;
- Whether prizes actually incentivises innovation;
- Whether developing country producers would be able to compete for prizes; and
- If prizes would divert funding from other initiatives, such as public-private partnerships.

13. The Research and Development (R&D) Treaty is aimed at addressing problems, including that R&D linked to drug prices strengthens the bargaining power of monopolies, raises the prices of medicines and leads to a rationing of access to medicines. Additionally, research directed at treatments for diseases and conditions that primarily concern poor people living in poor countries is inadequate. Participants examined different models for an R&D Treaty, including those structured around: simple multilateral agreement to fund R&D for neglected diseases; norms for open science (such as the FAO treaty on genetic resources); and an agreement to meet existing WHO norms on health research funding (the 2 percent rule). It was noted that such a treaty should have mechanisms for priority setting and address both innovation and access.

14. Discussion centred on how the R&D Treaty models described compare to other R&D Fund proposals, their potential benefits for certain countries, information gaps (such as, pricing of medicines and costs of clinical trials), possible steps towards setting up an R&D Treaty, and feasibility in the context of the IGWG.

15. The international finance facility (IFF) is a mechanism using capital markets to raise funds for clinical trials. Donor countries would make legally enforceable guarantees to make ODA payments 15-20 years in the future. These obligations are packaged as securities and sold to bond holders. It has been reviewed by several experts and several governments have expressed interest. Committees are already in place for the identification of projects and management of projects. Discussion relating to the IFF related to how developing countries might participate, the role and interest of for-profit firms, and the relationship to multilateral process.

16. Several basic assumptions about innovation and access to medical products need to be revisited and placed in a broader context, examined in light of economic trends and potential future scenarios, such as those relating to the nanotech revolution. More information is needed relating to each of the mechanisms, relating to scope, purpose, funding source, risk allocation, and options for implementation. Moreover, the details regarding each of the proposals should be provided in a simple format, especially for small delegations in the IGWG process.

IV. Maximising IP-Related Mechanisms

17. Patent pools are a multiparty agreement between two or more patent owners by which their patents are licensed as a package to one another or licensed as a package

to third parties. The package may be licensed out to third parties on a bilateral basis either directly by one of the partners of the pool or indirectly through an independent licensing authority. It was noted that the form of a patent pool should follow the intended function. Some functions might include to: increase market share, incentivize innovation, increase competition, lower prices, and improve generic market penetration. Lessons from the electronics industry shed light on the relative effectiveness of patent pools in fulfilling such functions. Participants explored several examples of proposed patent pools relating to medicines, including the SARS IP Working Group, the Essential Medical Inventions Licensing Agency (EMILA), and the UNITAID pool for AIDS medications.

18. TRIPS flexibilities are endorsed by the Doha Declaration of 2001, addressed in the CIPIH Report, and part of IGWG discussion. They can be divided into pre-grant and post-grant flexibilities. The pre-grant flexibilities include: the LDC transition period; administrative observations and opposition procedures; patentable subject matter; patentability criteria; possible options outside the patent system in cases of incremental innovations; patent claim construction, and disclosure of patented inventions. Post-grant flexibilities include exceptions to patent rights; parallel importation; compulsory licenses; control of patent abuses and anti-competitive licensing practices, and forms of protection of clinical test data. The implementation of TRIPS flexibilities rests on the general principle that countries have the freedom to determine the method of implementation within their own legal system and practice. Pre-conditions for implementation include political will, appropriate policies and institutions, and necessary human resources.

19. IP in the WTO originally reflected a mercantilist approach, where trade-offs reflected commercial, rather than public interests. The first time there was a debate on flexibilities was in a case involving Canada on the use of the Bolar-plus stockpiling exception. Cases relating to competition policy in South Africa triggered a discussion on the use of flexibilities and efforts to reaffirm flexibilities. The Doha Declaration ultimately reiterated and gave flesh to flexibilities in public health. Discussions considered how flexibilities have been dealt with and restricted in free trade agreements (FTAs) in relation particularly to patent terms and protection of undisclosed test data. Recently, there has been a reaction to the narrowing of flexibilities and is evidenced in the revisions of IP provisions in the FTAs with Panama and Peru. In the context of intergovernmental organizations and particularly the WHO, there seems to be different perceptions among different actors on the nature and scope of flexibilities.

20. Participants discussed further the general lack of knowledge about flexibilities, including what they are and how they can be implemented. They noted that there is often an immediate association between TRIPS flexibilities and compulsory licensing, when there is actually a policy space that countries may use to safeguard their public interests. It was felt that here is a need for greater awareness, capacity building, and a need for greater support from institutions such as WHO and WIPO. Participants also acknowledged that at the domestic level countries attempting to implement flexibilities have faced significant levels of pressure and scare tactics. Efforts should be made to educate the many officials who do not understand and are not prepared to deal with the controversy. It was highlighted by several participants how flexibilities

are commonly used in developed countries particularly with view of ensuring that patents are granted to truly innovative products and processes.

V. Achieving Global Drug Access and Research

21. One proposal for a sectoral deal on pharmaceuticals would capitalize on the purchasing power of public procurement authorities to incentivize the development of new health products for the poor. In addition, it would aim to seek buy-in from the pharmaceutical industry. The package would use global funds to pay, among others, for HIV vaccines, new malaria medicines, in places such as sub-Saharan Africa. Costs covered by these funds would be kept low through generic prices and TRIPS exemptions, and by streamlining regulatory processes. Additionally, pharmaceutical companies would receive a commitment that developed countries would pay prices that cover research and development of essential medicines. Such a strategy may require WTO agreement, discussion within international organizations, such as in the IGWG process.

22. There was discussion on some components that might be part of a global deal on pharmaceuticals. These included voluntary licensing and technology transfer; measure for addressing counterfeiting; subsidy market research; effective competition regimes; greater flexibility for countries at lower stages of development.

23. With the view of moving the process forward, participants agreed on a general framework for future action and summarized some of the mechanisms under discussion (see Annex A). They outlined several gaps including the need for more information on: the pharmaceutical industry and current trends in the market; supply chain issues; pricing of products and costs of clinical trials; how the patent system is really working at the national level; the economics of the various incentive mechanisms under consideration; the contexts in which each of the incentive mechanisms are useful; how the WHO, WTO, and WIPO should cooperate; barriers to innovation in the North and South. Additionally, they discussed at length the research gaps and action points outlined in the attached table (Annex B). They invited ICTSD, convener of the meeting, to disseminate the result of their work to delegations to the IGWG, the IGWG bureau, international organizations and stakeholders in general.



International Centre for Trade
and Sustainable Development

Annex A

Dr. Elil Renganathan
Executive Secretary
WHO's Secretariat on
Public Health Innovation
and Intellectual Property

Geneva, 9 November 2007

RE: Submission to the WHO Intergovernmental Working Group (IGWG) on Public Health, Innovation and Intellectual Property by the International Centre for Trade and Sustainable Development (ICTSD).

This submission derives from the main findings of the participants at ICTSD's Dialogue on "Fostering R&D and Promoting Access to Medicines: New Opportunities Through Innovation." On behalf of the participants of the Dialogue, I would like to formally present the enclosed recommendations to the IGWG.

On October 22-26, 2007, a small group of experts from WHO member states, civil society organisations, academics, health practitioners and industry representatives met at the Rockefeller Foundation Study and Conference Center in Bellagio at a Dialogue organised by ICTSD to consider a number of specific policy proposals in greater detail which would address, and reconcile, the objective of bolstering both innovation and access. The dialogue brought 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 was the need to allocate the costs of R&D fairly while promoting access to medicines.

In particular, the meeting focussed on how to ensure that future policy proposals and actions ensure an effective health-needs-driven environment delivering innovation plus access in relation to health goods (i.e. medicines and medical devices).

Participants identified the following key issues:

- How to address the problem that the patent system is currently not fulfilling its function of getting health goods to the people who need them.

- How to ensure that health needs are emphasized in overcoming barriers to innovation.
- How to enable developing countries to utilise the TRIPS flexibilities and avoid going beyond the requirements of TRIPS (so-called TRIPS plus) so as to maximise competition and access to low cost essential health products.
- How to refine the IGWG plan so that it more clearly identifies specific outcomes and actions to achieve them, allocates responsibilities, and sets out timescales to enable the WHA to agree on subsequent actions.
- How to ensure that the potential contributions of the relevant UN agencies and WTO are pulled together to achieve the objective of medical innovation plus ready access to the results of such innovation.

The participants considered that additional schemes should help by relaxing the link between recovering the cost of R&D and the price of the end product. Mechanisms discussed include: Prize funds, not for profit drug development partnerships, patent pools, an R&D Treaty, licenses of right, advance market commitment, proportionate R&D cost burden sharing and expansion of the generic market in developing countries.

The following table and annexes expand on these issues and are intended to assist stakeholders in keeping the broader picture and options in mind when considering specific proposals at the second meeting of the IGWG and beyond. The table and annexes represent a summary of proposals and recommendations made by the participants in their personal capacity and they do not necessarily reflect consensus.

For additional information on the meeting and further details on each of the proposals, please visit: http://www.iprsonline.org/ictsd/Dialogues/2007-10-22/2007-10-22_desc.htm. Additionally, we would like to invite you to review new research on topics under discussion at the IGWG, which can be found at: http://www.iprsonline.org/ictsd/Dialogues/2007-10-22/2007-10-22_doc.htm and includes:

- *Achieving Both Access and Research: A Sector Agreement in Pharmaceuticals*, by John Barton
- *Fostering R&D and Promoting Access to Medicines*, by Carlos Correa
- *Prize, Advanced Market Commitments, and Pharmaceuticals for Developing Countries*, by Aidan Hollis
- *Operationalising Patent Pools for ARVs*, by Warren Kaplan

ICTSD presents its compliments to the WHO and wishes you success in the IGWG deliberations.

Sincerely,



David Vivas-Eugui
Programme Manager on Intellectual Property Rights and Sustainable Development
The International Centre for Trade and Sustainable Development

Patent Pools

The present patent system places severe constraints on the ability of healthcare systems to access needed medicines. In particular, more than one patent is often required by a manufacturer in order to make a certain product. This can be exemplified by production of fixed dose combination drugs (e.g., certain antiretrovirals) containing different chemical elements that are patented by different patent owners. This requires a complex series of negotiations before production can begin. If the transactional costs of these licenses are too high, the product may be delayed or perhaps not even produced. This is clearly a disaster for the public health. One potentially important way to deal with this multiplicity of patents required to produce medicines is to create a scheme to collectively manage the required intellectual property (IP).

Patent pools are a way to manage the multiple constraints placed up medicine manufacturers, as described in the prior paragraph. A patent pool is an agreement between two or more patent owners to licence one or more of their patented IP as a package. In the most relevant form to improve access to medicines, multiple patents are collected that are essential to produce a medicine and the package of patent licences are licensed to third party manufacturers (e.g., makers of antiretrovirals (ARVs)). Patent pools are not novel structures. In the early part of the 20th century, most important manufacturing industries in the United States had patent pooling arrangements. Key components of the telecommunications industry are subject to patent pools. Several important proposals for medicines patent pools also exist. There are many practical reasons to create collective IP management structures and these include the possibility of lower prices, improved economies of scale; lower transaction costs of negotiating and administering licensing programmes; increased innovation; removing blocking patents and managing or eliminating litigation risks. Such arrangements may be used to address diseases that disproportionately affect developing countries.

Warren Kaplan, Center for International Health & Development Boston University School of Public Health

An Optional Prize Mechanism for Pharmaceuticals

An optional prize mechanism for pharmaceutical products including vaccines would offer a new way to reward innovators while ensuring access for the poor.¹

The mechanism would require annual funding fixed between \$2bn and \$10bn, with contributions from high- and medium-income country governments in relation to their income level. This funding would be dispensed in rewards to firms which offered zero-priced global licenses for relevant patents on innovative drugs, in proportion to the health impact of each drug. Each drug would be eligible for rewards for 10 years following its first commercial sale. An appointed Independent Assessment Committee would be responsible for estimating the incremental health impact of each product,

¹ For more information, see “A Comprehensive Advanced Market Commitment”, available at http://www.who.int/phi/public_hearings/second/contributions_section2/Section2_Aidan_Hollis_Full_Contribution.pdf.

using the best available methodology. Decisions on rewards, with reasons, would be published.

This approach would have many important effects. First, all products in this system could be competitively produced and sold, thus enabling wide access. Second, innovators would receive compensation directly based on the therapeutic impact of their product, with larger payments for more important products, thus stimulating valuable innovation. Third, the focus of this incentive mechanism would be products whose principal therapeutic impact would be in low- and medium-income countries. This is because products with high potential profitability from the patent monopoly would not be entered into this mechanism. In contrast, firms with products which were unlikely to be very profitable under patent exclusivity – such as those addressing neglected diseases – would find this mechanism highly attractive. If the mechanism were initially found to be successful, it could be expanded.

Aidan Hollis, University of Calgary

The R&D Treaty

One of the most important but also least understood and most controversial issues at the WHO IGWG concerns a treaty on medical R&D. Much of the controversy concerns a specific proposal for an R&D treaty that was made in February 2005, in a submission to the WHO signed by more than 160 academic experts, NGOs, policy makers and other stakeholders. This proposal would have created obligations on countries to support biomedical R&D, but left member states with broad discretion on how to implement their obligations. It also proposed a Kyoto style system of tradeable credits for countries that sponsored R&D in areas of medical priority, such as for neglected diseases. While many people have focused on this proposal, which received so much support, there have been many other proposals for R&D treaties with different objectives and approaches. Some of the proposals have narrow objectives, such as the funding of clinical trials for independent testing of existing drugs, or to provide longer term funding for R&D for priority medical needs. The public health community clearly needs to create a more formal structure for dealing with issues of priority setting, sustainable sources of funding, and norm setting in other areas. At this point, the WHO IGWG needs to keep the conversation open, and schedule meetings where governments will begin to discuss the possible elements for new international norms or agreements on medical R&D. This is difficult, in part because there are so many different ways this could proceed, and countries are unsure what they are being asked to endorse. The short term answer is to create a space where countries can propose and evaluate different approaches, without an expectation that decisions will be reached quickly on the outcomes, and without prejudice to different approaches. If the U.S., Europe and other high income countries are concerned that an R&D treaty is a threat to intellectual property rights, the IGWG could suggest, in its terms of reference, that the discussions should consider models for an R&D treaty that are consistent with country obligations, if any, under the WTO TRIPS agreement and the 2001 Doha Declaration on TRIPS and Public Health.

James Love, Knowledge Ecology International

A Sector Agreement in Pharmaceuticals

The developed world will inevitably bear most of the research costs for “international orphan drugs” for diseases primarily found in the developing world. It already bears a significant portion of distribution costs for such drugs through organizations such as the Global Fund for AIDS, TB, and Malaria (GFATM). Rather than creating new organizations to provide advance purchase commitments or prizes, why not look to such existing funds to commit themselves to purchase newly developed products at prices that provides incentives for the development of important new drugs? This requires the adoption of appropriate purchasing principles by the funds and the strengthening of donor nation commitments for financing.

The global funds and the public and private sectors in the poorest nations should, however, be able to obtain products at low generic prices when the research can be covered by sales in the developed world market. This is a matter of both equity and political sustainability. Hence, a second appropriate part of a package is to maintain a generic market for the poorest, as through appropriate exemptions under TRIPS.

Research is still needed for products to treat diseases that are common to the developed and developing world. The public health systems of many nations already impose price controls on such products, and it is likely that the United States (currently the largest market) will do so in the future. To avoid slowing medical research, these price controls should be shaped in ways that maintain research incentives. National government commitments to such price arrangements will not only support research but may also make the research-based pharmaceutical industry an ally of a package rather than an opponent. This makes negotiating a package more feasible.

These three commitments – to maintain a generic market for the poorest and to ensure that both the global funds and the national health services pay for pharmaceuticals in ways that encourage research -- form an economically defensible package. To produce an overall equitable balance, special arrangements may also be needed for the middle income nations. As they grow economically, these nations must at some point pay their full share of research costs. But some of these nations still include many very poor people, so it may be appropriate to make special transition arrangements such as allowing the public sector of these nations to have access to the lower-cost generic market or applying a shorter patent term.

This overall package supports both access and research, builds on existing institutions, and balances political and economic costs and benefits. It could be implemented in many ways; one approach is to combine the various commitments into a single agreement, which could be a sector-specific code within the WTO.

John Barton, Stanford University Law School

Funding the Development and Distribution of Medicines for Diseases neglected by commercial markets

Following the launch of the pilot International Finance Facility for Immunisation (IFFim), various private and public organisations have been advocating the establishment of an IFF for neglected diseases (IFFnd). The IFFnd is designed to raise funds to finance the high cost clinical development stages of medicines and diagnostics and at some time vaccines for malaria, TB, parasitic and similar neglected diseases through the international bond markets. As in IFFim, AAA-rated bonds would be structured and issued on international markets securitised against sovereign and similar highly rated pledges.

The front-loaded resources freed up through this mechanism would then fund the, currently critically under funded, late stage clinical development plus manufacture and introduction of approved medicines that emerge from successive portfolios pooled from Product Development PPPS and established Pharmaceutical organisations in developed and emerging economies. It is proposed these organisations combine their interests and a board of trustees trustee would select projects, administer the disbursement of funds and adjudicate the cessation of funds to medicines that fail predefined clinical development criteria.

It is estimated that IFFnd will require up to US\$4bn to be raised from bondholders, and should result in flow of medicines emerging with approval to market and then funded into manufacture and introduction. It is envisaged that the proportion of funds required from developed country governments would decrease over time, through increased income from fees paid by companies for the right to commercially distribute products developed through IFFnd, and through differential pricing as middle income countries and developing countries can afford to pay more for these products. It is predicted that increased investment in R&D for neglected diseases will have a positive affect on the rest of the logistics chain, through funders being able to see that treatments for neglected diseases are or will soon be available, therefore making investment in research and distribution systems and other areas worthwhile. The Global fund are seen as a key partner in the distribution process and IFFnd funding of development will enable a high level of control to be exercised over regional and sector pricing of approved medicines. Essentially the objective will be to approach near to generic pricing for medicines funded by IFFnd and the model proposed by Professor John Barton, Stanford, indicates how this objective might be realised.

Like IFFim, IFFnd does not need the participation of all the major international donors to commence and the successful launch of IFFim can smooth the way for IFFnd. There are significant benefits of frontloading aid for neglected disease R&D, as it will result in drugs and vaccines for these diseases being available sooner, which in turn will result in lower mortality and morbidity, and decrease the negative economic affects of these diseases on the economy of countries affected.

Peter Brown, SecureAid

TRIPS Flexibilities related to pharmaceutical products²

Pre-grant flexibilities
1. Use of transition periods in case of least developed countries 2013 waiver 2016 waiver
2. Administrative observations and opposition procedures*
3. Patentable subject matter a) Role of patent examiners b) Exclusions from patentability (27.2 and 27.3.a TRIPS) c) Definition of invention (treatment of new uses, new chemical entities)
4. Patentability criteria (Article 27.1) (novelty, inventive step, industrial application). Narrow or wide interpretation
5. Options outside the patent system in cases of incremental innovations: utility models, compensatory liability regimes
6. Patent claim construction: delimiting the boundaries of the invention
7. Disclosure of patented inventions: in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art (Article 29)

* Opposition procedures could also take place in the post grant phase

² Presentation at the Dialogue on the TRIPS flexibilities was based on a forthcoming publication (2007) by UNCTAD, entitled *Using Intellectual Property Rights to stimulate pharmaceutical production in developing countries: a reference guide*

Post Grant
1. Exceptions to patent rights (scientific research, experimental use; bolar or regulatory exception; medical treatment or medical practitioner) (Article 30)
2. Exhaustion of intellectual property rights: treatment of parallel imports (Article 6 and Doha Declaration)
3. Compulsory licensing (Article 31) -Doha regime
4. Control of patent abuses and anticompetitive licensing practices (Articles 8 and 40)
5. Protection of clinical test data (Article 39) -Misappropriation -Data exclusivity (FTAs) -Cost sharing

Pedro Roffe, ICTSD

Annex B



Fostering R&D and Promoting Access to Medicines
ICTSD Dialogue on New Opportunities through Innovation
22 – 26 October 2007, Bellagio, Italy

	Health R&D and Access
Research Gaps	<p>1. CLEARLY AND SUCCINCTLY EXPLAIN THE PROPOSED INCENTIVE MECHANISMS</p> <p>Provide a simple graphical comparison of the proposed mechanisms for incentivising R&D and promoting access to health goods (including, the Prize Fund, R&D Treaty, Patent Pools, Advanced Markets Commitments (AMCs), International Finance Facility, and the proposal for a global pharmaceutical deal³), describing their main features and possible variations, potential costs and benefits, advantages and disadvantages, and circumstances under which they would be most beneficial. In particular, identify those incentive mechanisms that are suitable for developing country markets.</p> <p>Increase understanding of how the mechanisms fit into the broader landscape of innovation and access.</p>

³ Please see the annexes A, B, C, and D for descriptions of some of the mechanisms.

If possible, test some of the mechanisms using pilot projects and/or by analysing hypothetical scenarios.

Identify incentives that take into account the limitations of developing country firms in health R&D and manufacturing, including subsidies, investment policy and technology transfer schemes.

Identify mechanisms for: improving technology transfer in the field of health research; addressing problems surrounding the migration of health professionals from developing to developed countries

2. USING EXISTING FRAMEWORKS BETTER

Explore how international organizations (e.g. WHO, WIPO, and WTO) could collaborate more effectively and to this end, identify what will be needed to facilitate cooperation

Identify projects in parallel to the IGWG, opportunities in other fora, and ways to improve policy coherence at all levels

3. ACT REGIONALLY AND NATIONALLY

Explore ways to make it is easier for developing countries to provide long term financial commitments in R&D, including issuing of debt, stocks and single fund contributions

Identify ways to improve the R&D capacity of SMEs and opportunities to exploit locally generated research

Take stock of existing projects and initiatives that are working; identify new and existing sources of funding

Create/strengthen regional health R&D centres that focus on regional priorities

	<p>4. INCREASE UNDERSTANDING OF THE PHARMACEUTICAL MARKET</p> <p>Promote transparency on resource flows and allocation, costs of clinical trials, and price structure in the pharmaceutical industry</p> <p>Outline future scenarios of the pharmaceutical sector and potential new models for innovation</p>
<p>Policy Actions</p>	<p>1. SET PRIORITIES</p> <p>Establish a process or mechanism for priority setting, in terms of diseases, research lines and type of incentives to be implemented</p> <p>Agree on criteria for evaluation of different incentives (i.e feasibility, efficacy and institutional framework and management)</p> <p>Create an IGWG project plan which outlines objectives, principles, structure, timeframes, and budget.</p> <p>Emphasize the objective of promoting development through the IGWG process.</p> <p>2. SEEK BROAD INVOLVEMENT</p> <p>Involve new stakeholders, such as insurers and regulatory authorities</p> <p>Do not isolate the IGWG process from other international discussions (i.e. WIPO Development Agenda)</p> <p>Ensure participation of health ministries in relevant IP international debates</p> <p>3. BUILD CAPACITY</p> <p>Build capacity for regional/national R&D health centres</p> <p>Facilitate new partnerships with SMEs (i.e. Chagas or new drugs discovery in Jordan)</p>

	<p>4. PROMOTE SAFETY AND QUALITY</p> <p>Involve developing country producers in discussions on international safety and quality standards and facilitate fulfilment of such standards</p>
	<p>IP-Related Issues and TRIPS Flexibilities</p>
<p>Research Gaps</p>	<p>1. INCREASE KNOWLEDGE OF THE CURRENT IP LANDSCAPE</p> <p>Explore how the patent system is actually operating, including at the patent office level and how it impacts health research and access</p> <p>Identify barriers to innovation and explore how best to overcome them</p> <p>Revisit the report of the UK Commission on intellectual property and take inventory of related developments during the last five years</p> <p>2. MEASURE IMPACT</p> <p>Assess the economic/development value of TRIPS flexibilities. Identify who is using them, which ones, and how.</p> <p>Evaluate the impact of patenting trivial developments on innovation and access</p> <p>Evaluate options for mitigating the impact of abusive injunctive relief mechanisms in the field of pharmaceutical patents</p>

	<p>3. IMPROVE QUALITY AND EFFICIENCY</p> <p>Explore options for national/international recognition of marketing approval by sanitary authorities with high levels of vigilance and based on publicly available information</p> <p>Improve understanding of the issue of counterfeiting and clarify the distinction between counterfeiting and patent infringement</p>
<p>Policy Actions</p>	<p>1. BE CLEAR ABOUT TRIPS-FLEXIBILITIES⁴</p> <p>Increase understanding of TRIPS flexibilities. Clearly articulate what they are and how they can be applied.</p> <p>Implement and provide incentives for the use of TRIPS flexibilities to promote public health</p> <p>Encourage WTO, WHO and WIPO to provide capacity building for effective implementation of TRIPS flexibilities</p> <p>2. BUILD ON PROGRESS THAT HAS ALREADY BEEN MADE</p> <p>Take action on components of WHO Commission on Intellectual Property, Innovation and Public Health report that can be implemented now</p> <p>Pursue outcomes that, under no circumstances, should include proposals that can be categorised as being TRIPS plus - meaning going beyond the minimum requirements of the WTO TRIPS Agreement</p> <p>Clearly express that the main objective of the IGWG is to promote development</p> <p>Acknowledge areas where agreement/consensus has already been made, such as in relation to the UK Commission on Intellectual Property, the WHO Commission on Intellectual Property, Innovation and Public Health, and in resolutions of the World Health Assembly</p>

⁴ See Annex E for a description of TRIPS flexibilities

