



International Centre for Trade
and Sustainable Development

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

Geneva, 8 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,

A handwritten signature in black ink, reading "David Vivas Eugui". The signature is written in a cursive style with a large initial 'D' and a distinct 'E' at the end.

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



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and Sustainable Development

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**

1. CLEARLY AND SUCCINCTLY EXPLAIN THE PROPOSED INCENTIVE MECHANISMS

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 deal¹), 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.

Increase understanding of how the mechanisms fit into the broader landscape of innovation and access.

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

¹ Please see the annexes A, B, C, and D for descriptions of some of the mechanisms.

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

4. INCREASE UNDERSTANDING OF THE PHARMACEUTICAL MARKET

Promote transparency on resource flows and allocation, costs of clinical trials, and price structure in the pharmaceutical industry

Outline future scenarios of the pharmaceutical sector and potential new models for innovation

**Policy
Actions**

1. SET PRIORITIES

Establish a process or mechanism for priority setting, in terms of diseases, research lines and type of incentives to be implemented

Agree on criteria for evaluation of different incentives (i.e feasibility, efficacy and institutional framework and management)

Create an IGWG project plan which outlines objectives, principles, structure, timeframes, and budget.

Emphasize the objective of promoting development through the IGWG process.

2. SEEK BROAD INVOLVEMENT

Involve new stakeholders, such as insurers and regulatory authorities

Do not isolate the IGWG process from other international discussions (i.e. WIPO Development Agenda)

Ensure participation of health ministries in relevant IP international debates

3. BUILD CAPACITY

Build capacity for regional/national R&D health centres

Facilitate new partnerships with SMEs (i.e. Chagas or new drugs discovery in Jordan)

4. PROMOTE SAFETY AND QUALITY

Involve developing country producers in discussions on international safety and quality standards and facilitate fulfilment of such standards

	IP-Related Issues and TRIPS Flexibilities
Research Gaps	<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-FLEXIBILITIES²</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>

² See Annex E for a description of TRIPS flexibilities

ANNEXES³

ANNEX A: 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

ANNEX B: 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.⁴

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

³ To access full-length proposals and presentations, please visit:
http://www.iprsonline.org/ictsd/Dialogues/2007-10-22/2007-10-22_doc.htm.

⁴ 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.

following its first commercial sale. An appointed Independent Assessment Committee would be responsible for estimating the incremental health impact of each product, 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

ANNEX C: 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

ANNEX D: 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

ANNEX E: 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

ANNEX F: TRIPS Flexibilities related to pharmaceutical products⁵

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

⁵ 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