Bridges, August 2008

**The Importance of the WHO Global Strategy on Public Health**

*One of the key negotiators in the talks that ultimately led to the newly adopted Global Strategy on Public Health, Innovation and Intellectual Property recently wrote to tell me that his services were no longer required because the job was done. Can we agree on this statement?*

Undoutedly not. True, the negotiators of the intergovernmental working group (IGWG) on this issue left us with a finalised Global Strategy, packed with action points that could fundamentally change how health research and development (R&D) is conducted – both in the way it is prioritised to ensure that it responds to real needs and in the way it is financed so that products that are developed are made accessible to those who need them. That is considerable progress – historical even. But the job is far from done. Real change, which after all will be the ultimate benchmark of the IGWG's success, will depend on how forcefully the World Health Organisation (WHO) and its member states will implement the strategy and translate it into action.

Of course, the IGWG did not work in a vacuum; its deliberations built on the work of others. The analysis of the current intellectual property (IP) and medical innovation environment made by the blue-ribbon Commission on Intellectual Property Rights, Innovation and Health (CIPIH) showed that something is fundamentally wrong with the way new health care products are developed and brought on to the market. In its 60 recommendations to start addressing both the access problems caused by the current IP environment and the lack of innovation, in particular for diseases that affect people in developing countries, the commission provided a firm basis for the IGWG to do its work. Some of the forcefulness of the CIPIH's evidence-based work was lost in translation as, inevitably, the action proposed by the working group reflects the compromises needed to keep everyone at the negotiation table. For example, where the Global Strategy states that intellectual property rights (IPRs) are an "important incentive for the development of new health-care products", the prestigious commission preceding it actually found "no evidence that the implementation of the TRIPS Agreement in developing countries will significantly boost R&D in pharmaceuticals" and that 'insufficient market incentives' were the decisive factor. The contrast could not be starker.

Still, the days of uncritical celebration of ever higher levels of IP as the one and only way to ensure innovation seem to be over. Here, the Global Strategy is a forceful call for change. It contains proposals for patent pools for upstream and downstream technologies to increase access and innovation, promotes the use of compulsory licensing to encourage competition in the pharmaceutical generics market, rejects TRIPS-plus measures in trade agreements, and encourages the development of new incentive mechanisms, such as prizes and government involvement setting in R&D priorities.

More ambitiously, the Global Strategy opens the door for fundamental change in two key areas.

Relationship between Cost and Price
First, building on World Health Assembly – the WHO's highest decision-making body – resolution 60.30, it calls for the development of proposals for health-needs-driven R&D, including "addressing the de-linkage of the costs of research and development and the price of health products."

Such a decoupling would break the cycle of financing R&D through high drug prices. As long as research and development depend on the ability to charge high prices, steering the current market-opportunity-driven R&D towards a more health-needs-driven approach will remain wishful thinking. It will also make it impossible to bring drug prices sustainably down, except through painstaking drug-by-drug, country-by-country battles.

Prizes are one way to achieve the delinking cost from price.1 Barbados and Bolivia made proposals to the IGWG for prizes to reward innovation. They suggested to start exploring multiple prizes: for the development of a low-cost rapid diagnostic test for tuberculosis; for new treatments for Chagas disease; for a priority medicines and vaccines prize fund to reward mechanisms for new cancer treatments in developing countries; and for a licensed products prize fund for donors.2 The strategy commits WHO member states to pursuing ideas such as these.

What is crucial is that on such issues, the strategy is likely to act as a catalyst for change by a range of different actors. Although the plan of action detailing how the Global Strategy will be implemented is not finalised, the very existence of the strategy is likely to create a certain momentum, or indeed resonance, to inspire other actors to grasp the thornier issues of access to medicines and IP.

One example is UNITAID, which is contemplating setting up a pharmaceutical patent pool, both to boost access to new antiretroviral (ARV) drugs to treat AIDS in developing countries and to develop fixed-dose combination and pediatric formulations of triple ARV therapy, even when the patents of the individual drugs are held by different entities. The strategy's call to explore new and alternative incentives for health R&D is also stimulating debate among academics and industry. In particular, the idea of awarding prizes, rather than monopolies, is gaining ground.3 At a recent expert roundtable convened by Médecins sans Frontières, tuberculosis researchers, economists and campaigners showed considerable interest in a proposal for a prize that would encourage the development of an easy-to-use point-of-care TB diagnostic test that would also be effective in diagnosing TB in people living with HIV/AIDS.

In sum, the idea of moving away from monopolies to awarding and incentivising innovation differently is gaining ground. This principle of de-linking R&D costs from the price is also practiced by not-for-profit developers such as the Drugs for Neglected Diseased Initiative, which pays for the R&D upfront and has a no patent policy with regard to the products that result from the research. This makes products available as generics from day one of marketing.

Elsewhere, Novartis has proposed to create a global fund for R&D for neglected diseases to support not-for-profit innovation. The proposal includes centralised portfolio and IP management. Beneficiaries of the fund would be required to license their intellectual property exclusively to the funding body for the neglected disease, but would have the right to exploit their IP in more affluent markets, provided that royalties are paid to the fund. If the new compound presents advantages in the treatment of a disease with greater commercial value, the inventor or company would compensate the fund for data developed with financing meant for neglected diseases.

Of course, the Novartis proposal focuses solely on neglected diseases and suggests only limited changes to the global R&D system. Nevertheless, the condition of access to the IP generated by the funded research to enable low-cost production and wide dissemination of the products is a clear recognition of the access problems created by IPRs. This is a new sound coming from the pharmaceutical industry.

TRIPS or Treaty?

The second fundamental change that the strategy may usher in is that it raises the possibility of intergovernmental talks about an essential health and biomedical treaty to change the rules of medical research and development.

Today's predominant global R&D treaty, the WTO's TRIPS Agreement, is based on granting monopolies as the main incentive for innovation; its provisions for technology transfer are limited. If one asks whether the TRIPS Agreement would come into being today, knowing what we know now about access and innovation, even its most ardent proponents would likely say no.

When WTO TRIPS Agrrement was negotiated, there was no public debate, the scale of the AIDS epidemic in developing countries was not known, and the understanding of the technical and legal details among health groups was virtually non-existent. In contrast, industrial interests were strongly represented and played a critical role in drafting the text and lobbying for its support.

Conversely, if today the parties to the TRIPS Agreement set out to design an international agreement on essential health R&D, the incentives would add to those in TRIPS and would likely be much more diverse and differ from those found in the TRIPS Agreement. This concept is at the heart of the proposals by Love and Hubbard for a new trade framework focused on equitable contribution to the cost of R&D through any means – not exclusively through the granting of patent monopoly rights.5 As a result, new products would be more widely accessible and not tied up in 20 year patents. There would be a market for R&D, and a separate, competitive market for production and sales in which all products may be generics. An R&D contribution norm established by an international treaty would ensure that the financial resources for R&D would be available, but these funds would no longer depend on high prices and thus rationing of the products.

Moving the debate from IP to R&D would affect countries' ability to shape the dynamics in trade agreements. When the talks are no longer centred on how high IP standards should be but, rather, on how can each country contribute to essential health innovation to benefit all, the discussion will change. In trade talks TRIPS-plus demands will become harder to maintain.

**Where Next for the World Health Organisation?**

The Global Strategy is, after the 2001 Doha WTO Declaration on TRIPS and Public Health, the most important multilateral attempt to alter IP policies so they respond better to real health needs. This time, the health authorities are leading the negotiations; the process takes place at World Health Organisation, not the World Trade Organisation. The strategy's success will thus depend on the WHO's forcefulness and resolve.

However, the organisation's role in all this remains highly controversial. In addition, countries have yet to fully agree who are the key stakeholders that should implement the different elements of the action plan for the strategy.

That the WHO has so far failed to acknowledge, translate and publish Bolivia and Barbados' prize fund proposals, although they were tabled in direct response to a 2007 World Health Assembly Resolution, does not bode well in this respect. Nor does the haggling seen during the negotiations over the WHO's mandate in the area of IP.

The Global Strategy is about action. The WHO, as the most important public health agency in the world, should take a leading role. Without forceful implementation, the strategy will remain nothing but a declaration of good intentions. Of those, the world has seen enough.

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endnotes

1 Stiglitz, Joseph. 2007. Prizes, Not Patents. 2007. http://www.project-syndicate.org/commentary/stiglitz81

2 Working document proposed by Barbados and Bolivia. 17 April 2008. http://www.keionline.org/

3 See supra note 1.

4 Paul Herrling, R&D and Sustainable, Predictable Financing of R&D for Neglected Diseases, note presented at the KEI, MSF, Global Forum for Health Research meeting on 28 March 2007 in Geneva.

5 Hubbard, T. and Love, J. A New Trade Framework for Global Healthcare R&D. PLoS Biol. 2004; 2:E52.